

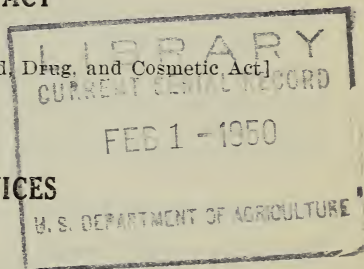
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FEDERAL SECURITY AGENCY**FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2671-2690

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *December 19, 1949.*

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 2672, 2673; failure to bear a label containing an accurate statement of the quantity of the contents, No. 2673; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2673.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2671. Misbranding of *Uvursin*. U. S. v. 53 Boxes * * *. (F. D. C. No. 26357. Sample No. 5391-K.)

LIBEL FILED: December 29, 1948, District of Rhode Island.

ALLEGED SHIPMENT: On or about September 16 and October 25, 1948, by the John J. Fulton Co., from San Francisco, Calif.

PRODUCT: 53 boxes, each containing 54 capsules, of *Uvursin* at Providence, R. I.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions which appeared in the labeling failed to reveal the disease or condition for which the article was to be taken.

DISPOSITION: March 2, 1949. Default decree of condemnation and destruction.

2672. Misbranding of Home Brand Laxative and Liver Tablets. U. S. v. 32 Cartons, etc. (F. D. C. No. 26459. Sample No. 44333-K.)

LIBEL FILED: February 7, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: On or about March 28, 1946, from St. Louis, Mo.

PRODUCT: 32 cartons, each containing 36 tablets, and 564 cartons, each containing 12 tablets, of *Home Brand Laxative and Liver Tablets* at Columbus, Ohio, in the possession of Theodore A. Wegener. The article was shipped in bulk and repackaged by the consignee.

Analysis showed that the article consisted essentially of extracts of laxative plant drugs, such as cascara sagrada, aloe, and podophyllum.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article was not effective in the treatment of the conditions and diseases stated and implied: (carton) "Liver Tablets * * * Aids in cleansing the stomach purifying the liver and regulating the bowels * * * For chronic constipation" and (leaflet enclosed in carton) "Liver Tablets * * * The Efficient Treatment for Relieving Stomach, Liver and Bowel Complaints. H. B. Laxative and Liver Pills is an excellent remedy for treatment of Bad Breath, Sour Stomach, Biliary Headache, Diseases of the Liver and Chronic Constipation * * * harmless * * * to insure freedom from Headache, heavy Stomach and that dark brown taste and a constipated condition."

Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), the labeling of the article failed to bear a warning against use of the article in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis, and it failed also to warn that frequent or continued use of the article may lead to dependence upon laxatives. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 1, 1949. Default decree of destruction.

2673. Misbranding of Stancrest Sulphur Bath Solution and Circulex Therapeutic Units (device). U. S. v. 24 Cans, etc. (F. D. C. No. 26583. Sample Nos. 14185-K, 14187-K.)

LIBEL FILED: March 22, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: The *Stancrest Sulphur Bath Solution* was shipped on or about October 27, 1948, by the Sulphur Products Co., Inc., from Greensburg, Pa., and the *Circulex Therapeutic Units* were shipped on or about August 28, 1948, by Barnett E. Laxer, from Buffalo, N. Y.

PRODUCT: 24 unlabeled gallon cans and 57 unlabeled quart cans and 4 labeled gallon cans and 17 labeled quart cans of *Stancrest Sulphur Bath Solution*, 500 *Stancrest Sulphur Bath Solution* labels, 23 *Circulex Therapeutic Units*, and 276 catalogs at Chicago, Ill., in possession of the Stanley Physical Therapy Equipment & Supply Co.

The unlabeled cans of the *Stancrest Sulphur Bath Solution* were to be labeled with the aforementioned labels at the time orders were received for the product. However, no labeling agreement such as is contemplated by the law and the regulations existed between the consignor and consignee. The catalogs were entitled "The Practical Physical Therapist February & March 1948 [or "January-February 1949"]" and were designed by the consignee for use in connection with the various products on sale by him.

Analysis showed that the *Stancrest Sulphur Bath Solution* consisted essentially of a lime-sulfur solution and that the device consisted of a metal case containing a motor, mounted off center, which produced a vibratory motion when operated.

LABEL, IN PART: "Stancrest Sulphur Bath Solution" and "Circulex Therapeutic Units."

NATURE OF CHARGE: *Stancrest Sulphur Bath Solution*. Misbranding (unlabeled cans), Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), it failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (e) (2), it was fabricated from two or more ingredients, and it failed to bear a label containing the common or usual name of each active ingredient. Further misbranding (labeled cans), Section 502 (a), certain statements on the label of the article and in the catalogs were false and misleading since they represented and suggested that the article was effective in the treatment of arthritis and all types of skin disorders, whereas it was not effective for such purposes. The article was misbranded under Section 502 (a) while held for sale after shipment in interstate commerce.

Circulex Therapeutic Units. Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use. The device was misbranded under this section when introduced into and while in interstate commerce. Further misbranding, Section 502 (a), the following statements in the labeling of the device "Treating Spine, Rectum, Anus, Prostate, Vagina, and other pelvic organs, for relief of aches and pains in the back and shoulders, treating legs for * * * varicose veins and other ailments, treating * * * aching feet and legs" were false and misleading since the device was not effective in the treatment of the diseases and conditions stated and implied. The device was misbranded under this section while held for sale after shipment in interstate commerce.

DISPOSITION: June 14, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2674. Adulteration of isotonic solution of sodium chloride and distilled water. U. S. v. 228 Bottles, etc. (F. D. C. No. 26254. Sample Nos. 46890-K, 46891-K.)

LIBEL FILED: January 3, 1949, Western District of New York.

ALLEGED SHIPMENT: On or about November 16, 1948, by Readyflask, Inc., from Lakewood, Ohio.

PRODUCT: 228 bottles of *isotonic solution of sodium chloride* and 356 bottles of *distilled water* at Buffalo, N. Y. Each bottle contained 50 cc. The products were packaged in flasks of a type intended for the administration of injections.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be "Sterile Isotonic Sodium Chloride Solution for Parenteral Use" and "Water for Injection," respectively, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and their quality and purity fell below the official standards since they were contaminated with undissolved material.

DISPOSITION: February 1, 1949. Default decree of condemnation and destruction.

2675. Adulteration of water for injection. U. S. v. 988 Vials * * *. (F. D. C. No. 26280. Sample No. 7856-K.)

LIBEL FILED: January 17, 1949, Western District of New York.

ALLEGED SHIPMENT: On or about October 23, 1948, from Decatur, Ill.

PRODUCT: 988 100-cc. vials of *water for injection* at Buffalo, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The product was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: February 16, 1949. Default decree of condemnation and destruction.

2676. Adulteration of Hepafer Vitamin B₁. U. S. v. 1 Box * * *. (F. D. C. No. 26388. Sample No. 4849-K.)

LIBEL FILED: January 6, 1949, District of Massachusetts.

ALLEGED SHIPMENT: On or about December 11, 1948, by Carlo Erba New York, Inc., from New York, N. Y.

PRODUCT: 1 box containing 72 ampuls of *Hepafer Vitamin B₁* at Springfield, Mass.

LABEL, IN PART: (Box) "Hepafer-Vitamin B₁ #2 * * * a sterile aqueous solution * * * Dosage and Administration: Intramuscularly"; (ampul) "Hepafer With Vitamin B₁ #2 * * * Intramuscular."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since the article purported to be and was represented as an aqueous solution intended for injection intramuscularly and was not suitable for such use. The

article was contaminated with undissolved material, whereas aqueous solutions intended for injection should be substantially free of undissolved material.

DISPOSITION: March 7, 1949. Default decree of condemnation and destruction.

2677. Adulteration of vitamin B complex. U. S. v. 88 Vials * * *. (F. D. C. No. 26386. Sample No. 48221-K.)

LIBEL FILED: January 5, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about November 17, 1948, by Carlo Erba New York, Inc., from New York, N. Y.

PRODUCT: 88 30-cc. vials of *vitamin B complex* at Philadelphia, Pa.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since the article was intended for parenteral administration and contained undissolved material, whereas an article intended for parenteral use should be substantially free of undissolved material.

DISPOSITION: February 8, 1949. Default decree of condemnation and destruction.

2678. Adulteration of Thiobismuth. U. S. v. 1 Box * * *. (F. D. C. No. 26383. Sample No. 11111-K.)

LIBEL FILED: On or about January 10, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about November 19, 1948, by Vincent Christina & Co., Inc., from New York, N. Y.

PRODUCT: 1 box containing 100 2-cc. ampuls of *Thiobismuth* at Jersey City, N. J.

LABEL, IN PART: (Box) "Thiobismuth Ampuls * * * Aqueous Solution of Sodium Bismuth Tartro-Amino Sulphone * * * For Intramuscular Use"; (ampul) "Thiobismuth For Intramuscular Use."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since the article was an aqueous solution intended for injection intramuscularly and was contaminated with undissolved material. Aqueous solutions intended for injection intramuscularly should be substantially free of undissolved material.

DISPOSITION: February 28, 1949. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration.

2679. Adulteration of Thiopentarsol and Thiosol. U. S. v. 21 Vials, etc. (F. D. C. No. 26236. Sample Nos. 30796-K, 30799-K.)

LIBEL FILED: January 5, 1949, Southern District of California.

ALLEGED SHIPMENT: On or about September 7, October 1, and November 5, 1948, from New York, N. Y.

PRODUCT: 21 100-cc. vials and 9 boxes, each box containing 24 2-cc. ampuls, and 17 boxes, each containing 12 2-cc. ampuls, of *Thiopentarsol*, and 14 100-cc. vials of *Thiosol* at Los Angeles, Calif.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the articles fell below that which they purported and were represented to possess since they were for parenteral administration and contained undissolved material, whereas articles represented to be for parenteral use should be substantially free of undissolved material. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: February 8, 1949. Default decree of condemnation and destruction.

2680. Adulteration and misbranding of prophylactics. U. S. v. 17 Cartons
* * *. (F. D. C. No. 26435. Sample No. 48232-K.)

LABEL FILED: January 31, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about November 24, 1948, by the National Hygienic Products Co., from Akron, Ohio.

PRODUCT: 17 cartons, each containing 48 packages of 3 *prophylactics* each at Philadelphia, Pa. Examination of samples showed that 3.8 percent were defective in that they contained holes.

LABEL, IN PART: (Package) "Texide Prophylactic * * * Manufactured By L. E. Shunk Latex Prod., Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "Prophylactic * * * Tested * * * For Your Protection" were false and misleading as applied to an article containing holes.

DISPOSITION: March 7, 1949. Default decree of condemnation and destruction.

2681. Adulteration and misbranding of prophylactics. U. S. v. 110 Gross * * *.
(F. D. C. No. 26562. Sample Nos. 19812-K, 19816-K.)

LABEL FILED: February 25, 1949, Middle District of Tennessee.

ALLEGED SHIPMENT: On or about August 8, 1948, by the Killashun Sales Division, from Akron, Ohio.

PRODUCT: 110 gross of *prophylactics* at Nashville, Tenn. Examination of samples showed that 4.2 percent were defective in that they contained holes.

LABEL, IN PART: "Texide Prophylactics Mfd. By L. E. Shunk Latex Prod., Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactic" was false and misleading as applied to an article containing holes.

DISPOSITION: April 29, 1949. Default decree of destruction.

2682. Adulteration and misbranding of prophylactics. U. S. v. 24 Gross * * *.
(F. D. C. No. 26539. Sample No. 29649-K.)

LABEL FILED: February 16, 1949, District of Colorado.

ALLEGED SHIPMENT: On or about February 17, 1948, by the Killashun Sales Division, from Akron, Ohio.

PRODUCT: 24 gross of *prophylactics* at Denver, Colo. Examination of samples showed that 6.9 percent were defective in that they contained holes.

LABEL, IN PART: "Texide Prophylactics Mfd. By L. E. Shunk Latex Prod., Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: April 18, 1949. Default decree of condemnation and destruction.

2683. Adulteration and misbranding of prophylactics. U. S. v. 76 Gross * * *.
(F. D. C. No. 26191. Sample No. 19780-K.)

LABEL FILED: December 2, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: On or about October 21, 1948, by the Goodwear Rubber Co., from New York, N. Y.

PRODUCT: 76 gross of *prophylactics* at Indianapolis, Ind. Examination of samples showed that 4.1 percent were defective in that they contained holes.

LABEL, IN PART: "Texide Manufactured by L. E. Shunk Latex Prod., Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "Prophylactic * * * Tested * * * for your protection", were false and misleading as applied to an article containing holes.

DISPOSITION: March 8, 1949. Default decree of forfeiture and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2684. Misbranding of Alberty's products. U. S. v. 6 Packages, etc. (F. D. C. No. 26381. Sample Nos. 27840-K to 27842-K, incl., 27845-K to 27848-K, incl., 27853-K to 27856-K, incl., 27858-K, 27860-K, 27862-K, 27863-K, 27865-K to 27867-K, incl.)

LABEL FILED: January 20, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about June 23, August 23, September 16, and October 8, 1948, by Alberty Food Products, from Hollywood, Calif.

PRODUCT: 6 packages of *Cheno Herb Tea Laxative*, 45 packages of *Cheno Combination Tablets*, 5 bottles of *Cheno Phytolacca Berry Juice Extract Tablets*, 22 bottles of *Alberty's Sabinol Homeopathic*, 7 boxes of *Alberty's Vitamin A Shark Liver Oil*, 54 bottles of *Alberty Phloxo B Tablets*, 6 bottles of *Ri-Co Tablets*, 3 cartons of *Instant Alberty Food*, 10 cartons of *Alberty's Food Regular*, 26 bottles of *Alberty's Lebara Pellets*, 27 bottles of *Alberty's Lebara No. 2 Pellets*, 3 bottles of *Alberty's Vi-C Tablets*, 3 bottles of *Recal Tablets*, 5 bottles of *Wheat Germ Oil*, 1 bottle of *R-Gon Tablets*, 7 bottles of *Alberty's Vitamin B₁ Tablets*, 7 bottles of *Alberty Vitamin B Complex Tablets*, and 3 bottles of *Alberty Riol Tablets* at St. Louis, Mo.

The products were accompanied by a number of booklets entitled "Dynamic Digests." These booklets had been shipped by the Alberty Food Products on or about July 17, 1948.

LABEL, IN PART: "Cheno Herb Tea Laxative Contains: Active Laxative ingredient Senna, combined with the following inactive ingredients: Kelp, licorice root, peppermint, fennel, anise, coriander, sassafras, ivy leaves, ononis, chick weed, black alder bark, beanshells," "Cheno Combination Tablets * * * Dehydrated Parsley, Swiss Chard, Dulce, Irish Moss, Spinach, Psyllium, Di-calcium Phosphate and Iron Phosphate," "Cheno Phytolacca Berry Juice Extract Tablets * * * Each Tablet contains the Extractives From Eight Drops of Phytolacca Berry Juice With Absorbents and Excipients," "Alberty's Sabinol Homeopathic * * * Each Pellet Contains: Berberis Vulgaris, Lycopodium, Uranium Nit, Equisetum," "Alberty's Vitamin A (High Potency) Shark Liver Oil * * * Each Perle Contains

*See also Nos. 2672, 2673, 2680-2683.

25,000 U. S. P. Units of Vitamin A," "Alberty's Phloxo B Tablets Vitamin B₁ with Homeopathic Amounts of Five Phosphates Each Tablet contains 40 Units of Vitamin B₁, 1/1000 gr. each of Phosphates of Iron, Potassium, Sodium, Calcium and Magnesium," "Ri-Co Tablets Homeopathic Combination * * * Each tablet contains Lithium Benzoicum, Ammonium Phos. Lycopodium," "Instant Alberty Food * * * Made with Dried Whole and Skim Milk and a Special Grind of Cereal (Wheat, Barley) and Dibasic Calcium Phosphate," "Alberty's Food * * * Contains special grind of cereal—Wheat, Barley, and Dibasic Calcium Phosphate," "Alberty's Lebara Pellets Homeopathic Contains Sodium Sulphate in Homeopathic amounts—1/1000 grain per pellet," "Alberty's Lebara No. 2 Pellets Homeopathic Principle Each Pellet Contains: Celandine Barberry Fringe-tree," "Alberty's Vi-C * * * Tablets * * * 30 Mg. Each Vitamin C," "Recal * * * Ingredients: Dicalcium Phosphate, Potassium Iodide, Irradiated Ergosterol, Sweetener, Citric Acid with excipients, Artificial Color and Flavoring. Six Tablets (Recommended Daily Intake) provide: Calcium . . . 1200 Mg. Phosphorus . . . 960 Mg. Iodine . . . 0.3 Mg. Vitamin D . . . 1000 U. S. P. Units," "3 Minim Perles Wheat Germ Oil," "R-Gon An Antacid Tablet * * * Ingredients: Magnesium Trisilicate, Calcium Carbonate, Bismuth, Subcarb., Magnesium Carb., and Flavoring," "Alberty's Vitamin B₁ * * * Six Tablets Provide: Vitamin B₁ . . . 1200 Inter. Units Vitamin B₂ . . . 0.21 Milligrams Niacin . . . 1.02 Milligrams Pantothenic Acid . . . 0.3 Milligrams Vitamin B₆ . . . 0.25 Milligrams," "Alberty Vitamin B Complex Tablets With High-Potency B₁ Each Tablet Supplies Vitamin B₁ . . . 500 U. S. P. Units Vitamin B₂ . . . 0.66 Mg. Vitamin B₆ . . . 0.1 Mg. Pantothenic Acid . . . 0.1 Mg. Niacin . . . 3.33 Mg.," and "Alberty Riol * * * Six Tablets Contain Vitamin C . . . 300 Milligrams (6000 U. S. P. Units) Niacinamide . . . 250 Milligrams Calcium . . . 700 Milligrams Phosphorus . . . 360 Milligrams Unsat. Fatty Acids . . . 5 Minims."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading. These statements represented and suggested that the articles would be effective for the following purposes, whereas they would not be effective for such purposes:

That the *Cheno Herb Tea Laxative*, the *Cheno Combination Tablets*, and the *Cheno Phytolacca Berry Juice Extract Tablets* were effective to reduce body weight;

That the *Alberty's Sabinol Homeopathic* was an effective treatment for urinary discomforts, dull achy feeling across the back, sharp pains in the kidneys, getting up frequently during the night, spots before the eyes, swelling of the feet, ankles, and lower limbs, dark circles beneath the eyes and puffiness, and lack of vitality; and that the article would exert a favorable action on the liver, promote the flow of bile, remedy renal (kidney) troubles and urinary discomforts, and increase the flow of urine and lessen its acidity;

That the *Alberty's Vitamin A Shark Liver Oil* was effective in preventing cirrhosis of the liver; was of benefit in liver disease; would decrease formation of kidney stones; would protect against colds; would effect speedy recovery from colds; would build resistance to infections of the sinuses, respiratory tract, and genito-urinary system; was an effective treatment for acne, sinusitis, colds, and bad eyesight; would help relieve tired, strained eyes; would aid sinus symptoms; would help build up resistance to colds; and would favorably affect tired eyes, dry skin, impairment of the teeth and bones, and lack of energy;

That the *Alberty Phloxo B Tablets* were effective in preventing long continued loss of sleep, disturbed sleep, premature old age, and insanity; in preventing the brain cells from losing their recuperative powers and their ability to eliminate the day's accumulation of waste products; and in preventing a depressed functioning throughout the whole system and the nervous system from becoming adversely affected; that they would give a soothing and relaxing effect; would induce natural and healthful sleep; would prevent the nerves from being starved; would prevent insomnia, nervousness, upset feeling, and irritability; would soothe and relax taut nerves; and would soothe irritability and nervousness and invite restful sleep;

That the *Ri-Co Tablets* were an effective treatment for arthritis, neuritis, rheumatism, chronic sepsis, a form of self-poisoning; would correct nutritional errors; would prevent the liver from being overworked and the kidneys becoming involved; would destroy toxic poisons; would prevent excess acid being released into the blood stream without being properly alkalized; would prevent deposits of earthy mineral substances accumulating in some of the joints; would prevent a form of rheumatism in which certain urates are found in the muscles, which become increasingly inflamed and painful; and would prevent stiff, painful, swollen, deformed joints, bones from wasting away, and overgrowth of bones, resulting in deformity of the joints;

That the *Instant Alberty Food* and the *Alberty's Food Regular* were an effective treatment for ulcers, colitis, hyperacidity, ulcerated stomach, anemia, and a general run-down condition in persons recovering from malaria fever; that they would be effective for curing in 8 months duodenal ulcers of five years standing; that they would be effective in the treatment of tuberculosis and stomach trouble; that in combination with *Alberty Phloxo B Tablets* and *Alberty's Lebara Pellets*, they would be effective to remedy deficiency conditions where certain cells, tissues, and glands had been affected through the medium of the nervous system, blood, cells, and tissues, liver, kidneys, and other glands of the body; that in combination with the *Alberty Phloxo B Tablets*, the *Alberty's Lebara Pellets*, and the *Alberty's Sabinol Homeopathic*, the articles would be effective to remedy urinary discomforts; and that in combination with the *Alberty Phloxo B Tablets*, the *Alberty's Lebara Pellets*, and the *Ri-Co Tablets*, the articles would be effective to remedy arthritis and rheumatism;

That the *Alberty's Lebara Pellets* and the *Alberty's Lebara No. 2 Pellets* were an effective treatment for conditions of the liver which prevent toleration of fats, sweets, and starches; chronic indigestion due to dysfunctions of the liver; abused liver, which could no longer protect the body; overworked liver which was not able to prevent harmful toxic wastes and material from the bile entering the blood stream and creating a toxic condition and a yellowish discoloration of the skin and the whites of the eyes; jaundice, inactive liver, and other liver ailments such as biliousness, intestinal indigestion, malassimilation, dropsy, and toxemia; liver and gall bladder disorders leading to the development of gallstones; disease of the gall bladder and stomach disorders resulting therefrom; disease of the liver; and sallow or acid complexion; that the articles would render the liver healthy and thereby render the skin clear and the eyes bright and clear; and that they would keep the liver cells in an active healthy condition so that they could render harmless all the poisons and acids that the blood receives from the digestive tract and thus prevent the individual from becoming toxic or developing other symptoms of a deranged liver;

That the *Alberty's Vi-C Tablets* were an effective treatment for weak and bleeding capillaries; a tendency to bruise easily and to hemorrhage; red, swollen, and possibly bleeding gums; lowered resistance; reduced hemoglobin and a tendency to anemia; aching bones and joints; tooth decay; and chronic fatigue; that they would be effective for producing clear reasoning, especially in times of mental strain; in giving health and strength to the soft and connective tissues; in aiding in the nutrition of the thyro-adrenal system; in enabling the bone marrow to produce needed cell forms and the blood to take up oxygen from the lungs and expel carbon dioxide; for producing hair growth and coloring; for aiding the formation of hemoglobin; for lowering the blood sugar level in diabetes; for counteracting many body poisons; and for bringing relief in many stubborn cases of hay fever, asthma, and other forms of allergy.

That the *Recal Tablets* were an effective treatment for below-par conditions due to an overacid condition; that they would be effective to prevent or correct changes in the hormones, including those secreted by the thyroid, parathyroids, testicles, ovaries, pituitary, and adrenals, resulting from severe and long-continued overacid conditions causing lowered resistance to infections, ailments, and disease; that they would obviate the effects of excess acid on the cells of the body; that they would be effective to upbuild the cells and tissues and to obviate the effects of an excessive amount of acid which inhibits normal tissue changes and cell reproduction; that they would be effective for maintaining the blood's capacity to carry oxygen; for preventing irritation of the nerves; for aiding in complete assimilation of fats; for assistance in the elimination of toxic poisons and other waste products; and in preventing one or more of a great variety of disorders, including neuritis, rheumatism, gout, kidney involvement, asthma, heart trouble, inflammation of the gall bladder, ulcers, and abscesses; and that they would favorably affect all forms of disease, acute and chronic;

That the *Wheat Germ Oil* was an effective treatment to favorably affect the workings of the brain and to produce quick, brilliant minds; to favorably affect one's intelligence; by administration to the mother to render her offspring more capable of acquiring intelligence; to liven the mental faculties; to favorably affect the bodies and minds of those unfortunates suffering from dementia praecox; to restore in some measure fertility in cases of dementia praecox before sterility had set in; to effect a general improvement of all functions of the body, muscular vigor and mental reorganization; to prevent sterility; to bring happiness to married couples whose homes lack the children they want; to prevent miscarriages; to favorably affect the development of the internal organs and sex glands, the quality and quantity of mother's milk, growth and development, and the functioning of the thyroid gland and pancreas; to give relief in or to cure certain types of paralysis in humans; to give relief to primary fibrositis which cripples the muscles and to completely rid many patients of the disease; and to prevent muscular atrophy in children;

That the *R-Gon Tablets* were an effective treatment for ulcers of the stomach and duodenum and for prevention of perforation peritonitis;

That the *Alberty's Vitamin B₁ Tablets* and *Alberty Vitamin B Complex Tablets* were an effective treatment for producing general fitness; to affect metabolism, growth, and development; to improve the appetite and nutrition; to effect gain in weight; to tone the digestive tract; to increase endurance and energy and to supply essential needs of the glands, vital organs, and nervous system; to benefit certain cases of heart disease and some cases of

arthritis and neuritis; to increase the body's insulin output and sugar tolerance in cases of diabetes; and to treat mental cases and to improve the intelligence of school children;

That the *Alberty Riol Tablets* were an effective treatment for hay fever, sneezing, blowing, and sniffing; and that they would be effective to allay the distressing symptoms of hay fever, asthma, and other allergies.

DISPOSITION: February 11, 1949. Default decree of condemnation and destruction.

2585. Misbranding of mixed natural estrogens. U. S. v. 8 Vials * * *. (F. D. C. No. 26461. Sample No. 28066-K.)

LIBEL FILED: February 14, 1949, District of New Mexico.

ALLEGED SHIPMENT: On or about November 29, 1948, by Henry C. Haist & Co., from Kansas City, Mo.

PRODUCT: 8 30-cc. vials of *mixed natural estrogens* at Albuquerque, N. Mex.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Mixed natural estrogens" and "consisting principally of Estrone and Estradiol derived from pregnant mare's urine" were false and misleading since the estrogens present in the article were not mixed natural estrogens and were not obtained from pregnant mare's urine; and the label statements "Estrogens in aqueous microsuspension" "very fine crystalline aqueous suspension," and "Aqueous solvent" were false and misleading since the suspending medium was not water but was a mixture of water, propylene glycol, and benzyl alcohol.

DISPOSITION: March 14, 1949. Default decree of condemnation and destruction.

2686. Misbranding of Miracle Oil and Miracle Inhalers. U. S. v. 1,007 Bottles, etc. (F. D. C. No. 26462. Sample Nos. 44341-K, 44350-K to 44352-K, incl.)

LIBEL FILED: February 8, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: On or about January 4 to 7, 1947, and on or about January 11 and 28 and February 2, 1949, from New York, N. Y.

PRODUCT: 1,511 1-ounce bottles, 144 2-ounce bottles, 249 4-ounce bottles, and 23 8-ounce bottles of *Miracle Oil*, and 2,016 *Miracle Inhalers*, at Columbus, Ohio. There were on display with the products various posters relating thereto which were prepared on instructions of Mr. Irving Gartman, a demonstrator for the products.

Examination showed that the *Miracle Oil* consisted essentially of volatile oils, including eucalyptus, camphor, and menthol, and that the *Miracle Inhaler* was a glass tube, constricted at one end, with cotton between the corks.

LABEL, IN PART: (Bottle) "Miracle A combination of Oil of Miracle Oil of Eucalyptus, Oil of camphor menthol Oil of peppermint thymol" and "Miracle Inhaler. Directions: Insert a few drops of Miracle Oil Compound into filler end of inhaler tube."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements and design appearing in the various posters on display with the articles were false and misleading since the articles were not effective in the treatment of the diseases and conditions stated and implied: "Miracle Eucalyptus Compound! Head Colds. Hay Fever. Arthritis. Ear Ache. Sinus. Rose Fever. Neuritis. Chest Colds. Asthma. Rheumatism. Sprains. L u m b a g o. Sinus

and Head Colds are Bad. Eucalyptus Oil Compound. * * * Catarrh * * * Bronchitis. * * * Sinus Infection. * * * Swollen Joints. Sciatica. Bursitis. * * * *Encyclopedia Britannica*. Eucalyptus oil has been given internally in pulmonary tuberculosis, and other microbic diseases of the lungs and bronchial tubes. * * * *Encyclopedia Americana*. Eucalyptus oil is used for its antiseptic * * * properties. It is very widely used in affections of the nose * * * *Forest and Culture* by Cooper. In Valencia, Spain, the eucalyptus tree is known as the fever destroying tree on account of its properties for preventing malarial fever * * * [Sectional drawing of head, neck, and chest, with legends] Sinusitis (C) Rhinitis. Tonsillitis. Laryngitis. Tracheitis. Lobar-Pneumonia (C). Broncho-Pneumonia (C). Emphema (C). Otitis Media. Mastoiditis. Adenoids. Pharyngitis. Adenitis. Bronchitis. Pleurisy. Types of colds take their names from the organs or parts of the body affected * * * designated (c) are complications. Other complications are neuritis * * * Myositis (inflammation of the muscles) and arthritis (inflammation of the joints)." The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 24, 1949. Default decree of destruction.

2687. Misbranding of Infra-Red Heat Applicator. U. S. v. 137 Cartons, etc. (F. D. C. No. 26364. Sample No. 29366-K.)

LIBEL FILED: January 6, 1949, District of Colorado.

ALLEGED SHIPMENT: By Sibert & Co., from East Orange, N. J. The device was shipped on or about September 2, 1947, and quantities of printed matter were shipped on or about June 1 and September 2, 1947.

PRODUCT: 137 cartons, each containing an *Infra-Red Heat Applicator*, together with copies of leaflets entitled "The True Beauty Aid for All Women," "How to Use It and Why," "Earn extra profits giving Therm-Massage Treatments," "Amazing New Scientific Invention," and "Customers go for," copies of a reprint entitled "\$200 Per Week Extra Profit," copies of a reprint from the Boston Post of April 23, 1947, copies of a reprint from the New York Times of February 23, 1947, copies of a circular letter entitled "Specialty Sales Company," and copies of a display placard entitled "Therm-Massage Heat Applicator."

Examination showed that the device consisted of two pieces of molded bakelite, one serving as the handle and the other containing an electrically heated coil.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since the device would not fulfill the promises of benefit stated and implied. The statements contained in the above-mentioned printed matter represented and suggested that the device would be efficacious in the cure, mitigation, and treatment of rheumatic pains, sore throat, arthritis, headaches, sinus, colds, muscular aches and pains in the back, sprains and bruises, neuritis, neuralgia, rheumatism, stiff neck, cramps in the feet and legs, bursitis, muddy complexion, skin blemishes, and stiff joints; and that the device would relax facial muscles, help prevent wrinkles, ease aches and pains caused by a sluggish system, invigorate the entire system, bring fresh food to nerves and tissues, stimulate the system to more vigorously fight disease germs, relieve pains of almost any kind, soothe tortured aching nerves and muscles, arouse and stimulate the blood circulation to greater activity, speed up the body process of carrying off the poisons of fatigue and

waste matter, make stiff and aching muscles supple and free again, restore circulation, and cause new life and blood to come to the tissues.

DISPOSITION: February 24, 1949. Default decree of condemnation and destruction.

2688. Misbranding of Infra-Red Heat Applicator. U. S. v. 11 Cartons, etc. (F. D. C. No. 26361. Sample No. 29364-K.)

LIBEL FILED: January 6, 1949, District of Colorado.

ALLEGED SHIPMENT: On or about September 2, 1947, by Sibert & Co., from East Orange, N. J.

PRODUCT: 11 cartons each containing a device known as *Infra-Red Heat Applicator* at Pueblo, Colo., together with copies of leaflets entitled "The True Beauty Aid for All Women" and "How to Use it and Why." This product was a small electrically heated device made of bakelite. It was intended for the application of heat to various parts of the body.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the device were false and misleading since the device would not fulfill the promises of benefit stated and implied. The statements represented and suggested that the device would relieve colds, sinus, rheumatic pains, muscular aches and pains, stiff neck, sore throat, and pains in the back; that it would improve circulation; that it was the true beauty aid for all women; that it would relax the tiny muscles of the face, throat, and neck, and thus aid in preventing the formation of wrinkles; that it would speed the removal and elimination of accumulated waste products which so often are the cause of sallow muddy complexions and skin blemishes; that it would preserve youth and beauty; that it would relieve pain of almost any kind and soothe tortured aching nerves; that it would speed up the body process of carrying off the poisons of fatigue and waste matter; that it would invigorate the entire system and bring fresh food to the nerves and tissues; that it would stimulate one's system to fight more vigorously the disease germs which find their way into the body; that it would enable stiff aching muscles to become supple again; that it would relieve most headaches with startling speed, even nervous headaches in the cerebellum or back of the head; that the device would relax the muscles, relieve the pain, and stimulate the blood circulation into carrying off the poisons of oxidation; that it would aid nature in its burden of carrying away the germ laden mucus secretions which congest the sinus process and unblock those tiny canals; that it would aid in relieving discomfort and congestion; and that it would be efficacious to relieve sprains, bruises, arthritis, bursitis, neuritis, and neuralgia.

DISPOSITION: February 24, 1949. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

2689. Misbranding of Yeastex. U. S. v. 600 Bags * * *. (F. D. C. No. 26377. Sample Nos. 29721-K, 29722-K.)

LIBEL FILED: January 4, 1949, District of Colorado.

ALLEGED SHIPMENT: On or about November 12, 1948, by the Yeastex Co., from Monticello, Iowa.

PRODUCT: 600 100-pound bags of *Yeastex* at Denver, Colo. Examination showed that the product was an animal feed mixture consisting essentially of moisture, ash, fat, protein, and crude fiber.

LABEL, IN PART: (Bags) "Yeastex * * * A High fermentative live-cell yeast culture"; (tag) "Yeastex-G" or "Yeastex."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they suggested and implied that the article would be effective in the prevention and treatment of intestinal, digestive, and other diseases of poultry, hogs, cattle, and dogs, whereas the article would not be effective for such purposes.

A portion of the article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: February 25, 1949. The Yeastex Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

2690. Misbranding of Security Special Udder Formula. U. S. v. 10 Jars, etc. (F. D. C. No. 24712. Sample No. 4804-K.)

LABEL FILED: April 7, 1948, District of Massachusetts.

ALLEGED SHIPMENT: On or about January 9, 1948, by the Security Remedies Co., from New York, N. Y.

PRODUCT: 10 1-pound jars of *Security Special Udder Formula* at Greenfield, Mass., together with a number of circulars entitled "Save the Udder and you save the Cow" and a number of posters entitled "Security Udder Formula." Analysis indicated that the product consisted essentially of petroleum, with small amounts of phenol, eucalyptol, bismuth, and zinc, and traces of aluminum, lead, and ichthammol.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars and posters were false and misleading since they represented and suggested that the article was effective in the treatment and prevention of mastitis of dairy cows and swollen and caked udders. The article was not effective in the treatment and prevention of such conditions of cows.

DISPOSITION: August 31, 1948. Default decree of condemnation and destruction.

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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2691-2710

DRUGS AND DEVICES

U. S. DEPARTMENT OF AGRICULTURE

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., December 19, 1949.

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DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2691. Alleged misbranding of Penicillin Oil Vehicle with Wax and Penicillin Oil Vehicle. U. S. v. E. S. Miller Laboratories, Inc., and Ernest D. Reason. Pleas of not guilty. Tried to the court. Verdict of not guilty. (F. D. C. No. 25592. Sample Nos. 86452-H, 31225-K.)

INFORMATION FILED: December 10, 1948, Southern District of California, against E. S. Miller Laboratories, Inc., Los Angeles, Calif., and Ernest D. Reason, vice president and general manager of the corporation.

ALLEGED SHIPMENT: On or about April 7 and November 12, 1947, from the State of California into the States of Arizona and Colorado.

*For presence of a habit-forming narcotic without warning statement, see Nos. 2693-2695; omission of, or unsatisfactory, ingredients statements, No. 2696; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2692, 2694-2696; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 2692, 2694-2696.

NATURE OF CHARGE: *Penicillin Oil Vehicle with Wax*. Misbranding, Section 502 (a), the following statements in the labeling "Sterile Oil Vehicle for Penicillin. A refined cholesterized cottonseed oil containing white wax 2% (W/V)," "Penicillin Oil Vehicle, a neutral cholesterized vegetable oil with 2% white wax," and "Penicillin Oil Vehicle (with wax) Penicillin Oil Vehicle is a neutral vegetable oil containing white wax 2% (W/V) and an absorption base which forms an emulsion with an aqueous solution of penicillin" were false and misleading. The statements represented and suggested that the article when used as a vehicle for penicillin, according to directions, namely, "Add only enough sterile distilled water to the penicillin to form a solution, usually 0.2 to 0.3 cc. are required. If the wax crystallizes out of the solution, warm the ampul in warm water to liquefy. Fill a syringe with the desired amount of the oil solution and empty it into the vial containing the penicillin solution. Shake well and a perfect easy flowing emulsion will result," would produce the same results as those produced by the penicillin in an oil wax base which is in common and general use by the medical profession, and which would in ordinary circumstances maintain the effective penicillin blood levels for a period of approximately 24 hours. The article when used as a vehicle for penicillin, according to the directions, would not produce the same results as those produced by penicillin in an oil wax base in common and general use since the article when mixed with penicillin, in accordance with the directions, would not maintain the effective penicillin blood levels for a period of approximately 24 hours but would maintain the effective penicillin blood levels for a much shorter period. Further misbranding, Section 502 (a), the labeling of the article was misleading since it failed to reveal the extent to which the article would maintain effective penicillin blood levels, which fact was material in the light of the representations in the labeling which conveyed the impression that the article when used as directed, would produce penicillin in an oil wax base which is generally recognized as capable of prolonging the effective penicillin blood levels for a period of approximately 24 hours; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to state the frequency with which penicillin in combination with the article should be injected.

Penicillin Oil Vehicle. Misbranding, Section 502 (a), the statements in the labeling "Penicillin Oil Vehicle. A neutral cholesterized vegetable oil," "Penicillin Oil Solvent," and "Penicillin Oil Solvent is a neutral vegetable oil containing an absorption base which forms an emulsion with an aqueous solution of penicillin" were false and misleading. The statements represented and suggested that the article when used as a vehicle for penicillin, according to directions, namely, "Add only enough sterile distilled water to the penicillin to form a solution, usually 0.2 to 0.3 cc. are required. Fill a syringe with the desired amount of oil and empty it into the vial containing the penicillin solution. Shake well and a perfect, easy flowing emulsion will result," would prolong the action of penicillin in the body. The article when used as a vehicle for penicillin, according to the directions, would not prolong the action of penicillin in the body. Further misbranding, Section 502 (a), the labeling of the article was misleading since it failed to reveal the extent to which the article would maintain effective penicillin blood levels, which fact was material in the light of the representations in the labeling which conveyed the impression that the article when used as directed would prolong the action of penicillin in the body; and, Section 502 (f) (1), the labeling failed to bear adequate

directions for use since it failed to state the frequency with which penicillin in combination with the article should be injected.

DISPOSITION: February 19, 1949. Pleas of not guilty having been entered, the case came on for trial before the court without a jury on February 16, 1949. At the conclusion of the trial, the court returned a verdict of not guilty.

2692. Misbranding of benzedrine sulfate tablets and thyroid tablets. U. S. v. Ray's Pharmacy, Ray S. Gresham, and Ben B. Western. Pleas of nolo contendere. Fine of \$250 against pharmacy and \$125 against each individual. (F. D. C. No. 25323. Sample Nos. 26387-K, 27023-K.)

INFORMATION FILED: On or about November 9, 1948, Eastern District of Missouri, against Ray's Pharmacy, a partnership, Macon, Mo., and Ray S. Gresham and Ben B. Western, members of the partnership.

INTERSTATE SHIPMENT: On or about February 19 and 24, 1948, from Philadelphia, Pa., and Tuckahoe, N. Y., of quantities of *benzedrine sulfate tablets* and *thyroid tablets*.

LABEL, WHEN SHIPPED: "Benzedrine Sulfate Tablets [or "Thyroid, U. S. P. Compressed"] * * * Caution: to be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about April 26, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused a number of tablets of the drugs to be removed from the bottles in which they had been shipped, to be repacked into boxes, and to be sold to various persons without a prescription, which acts of the defendants resulted in the tablets being misbranded. The repackaged tablets were labeled "Rays Benzidine Sulfate 5 Mg." and "B & W Thyroid 1 grain."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the boxes containing the repackaged tablets bore no labeling containing directions for use; Section 502 (b) (1), the label of the repackaged tablets bore no statements containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), the label of the repackaged tablets bore no statements of the quantity of the contents.

DISPOSITION: May 23, 1949. Pleas of nolo contendere having been entered, the court imposed a fine of \$250 against the pharmacy and \$125 against each individual.

2693. Misbranding of seconal sodium pulvules. U. S. v. Keene Pharmacal Co. (Harold Lloyd's Prescriptions), and Harold A. Lloyd, John M. Hilsher, and Percy L. Stogsdill. Pleas of nolo contendere. Corporation fined \$200 on count 1 and total of \$500 on counts 2 to 6; payment of \$500 suspended and corporation placed on probation for 1 year. Each individual defendant fined \$100. (F. D. C. No. 25594. Sample Nos. 22376-K, 22378-K, 22379-K, 22381-K, 22384-K, 22386-K.)

INFORMATION FILED: January 26, 1949, Northern District of Texas, against the Keene Pharmacal Co., a corporation, commonly known as Harold Lloyd's Prescriptions, Dallas, Tex., and against Harold A. Lloyd, president of the corporation, and Percy L. Stogsdill and John M. Hilsher, pharmacists.

INTERSTATE SHIPMENT: Between the approximate dates of January 28 and February 14, 1948, from Indianapolis, Ind., to Dallas, Tex., of quantities of *seconal sodium pulvules*.

LABEL, WHEN SHIPPED: "Pulvules Seconal Sodium 1½ grs. (0.1 Gm.) * * * Eli Lilly And Company Indianapolis."

ALLEGED VIOLATION: On or about March 3, 5, 9, 15, 19, and 22, 1948, while the drug was being held for sale after shipment in interstate commerce, the defendants caused a number of pulvules of the drug to be removed and to be repacked in boxes and caused them to be sold to various persons without a physician's prescription, which acts of the defendants resulted in the drug being misbranded. The repacked *seconal sodium pulvules* were labeled in part "Harold Lloyd's Prescriptions * * * No. 378919 Dr. Prejean * * * One each night before retiring [or "One capsule each night before retiring" or "Take one capsule each night before retiring"]."

NATURE OF CHARGE: Misbranding, Section 502 (d), the article was a drug for use by man and contained a chemical derivative of barbituric acid, which derivative has been found by the Administrator of the Federal Security Agency, after investigation, to be and by regulations designated as, habit forming, and the label of the repacked pulvules failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; Section 502 (f) (1), the labeling of the repacked pulvules failed to bear adequate directions for use since the directions for use on the labeling quoted above for the repacked pulvules were not adequate; and, Section 502 (f) (2), the repacked pulvules bore no labeling containing warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: January 27, 1949. Pleas of nolo contendere having been entered, the court imposed against the corporation a fine of \$200 on count 1 and a total fine of \$500 on counts 2 through 6, with payment of the \$500 fine to be suspended, and placed the corporation on probation for 1 year. The court imposed also a fine of \$100 against each of the individual defendants.

2694. Misbranding of seconal sodium pulvules. U. S. v. James Martin Pillers (J. M. Pillers & Son City Drug Store). Plea of guilty. Fine, \$300. (F. D. C. No. 25324. Sample Nos. 26371-K, 26379-K, 27006-K.)

INFORMATION FILED: November 24, 1948, Eastern District of Illinois, against James Martin Pillers, trading as J. M. Pillers & Son City Drug Store, Pinckneyville, Ill.

INTERSTATE SHIPMENT: On or about January 13, 1948, from St. Louis, Mo., to Pinckneyville, Ill., of a quantity of *seconal sodium pulvules*.

ALLEGED VIOLATION: On or about February 23 and 26, 1948, while the pulvules were being held for sale after shipment in interstate commerce, the defendant caused a number of pulvules to be removed from the bottle in which they had been shipped, repacked them into boxes, and sold them to various persons without a prescription, which acts of the defendant resulted in the pulvules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the label of the repackaged pulvules bore no statement containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), it bore no statement of the quantity of the contents; Section 502 (d), the pulvules were a drug for use by man and contained a chemical derivative of barbituric acid, which derivative has been found by the Administrator of the Federal Security

Agency, after investigation, to be and by regulations designated as, habit forming, and the label of the repackaged pulvules failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; and, Section 502 (f) (1), the boxes containing the repackaged pulvules bore no labeling containing directions for use.

DISPOSITION: December 14, 1948. A plea of guilty having been entered, the court imposed a fine of \$300.

2695. Misbranding of amytal and acetyl-salicylic acid capsules, nembutal sodium capsules, and benadryl hydrochloride capsules. U. S. v. Richard C. Miller (Miller's Rexall Drug Store). Plea of nolo contendere. Fine, \$500. (F. D. C. No. 25327. Sample Nos. 26395-K, 27008-K, 27022-K.)

INFORMATION FILED: December 4, 1948, Eastern District of Missouri, against Richard C. Miller, trading as Miller's Rexall Drug Store, Macon, Mo.

INTERSTATE SHIPMENT: Between the approximate dates of June 20, 1947, and March 9, 1948, from the States of Indiana, Illinois, and Michigan, into the State of Missouri.

LABEL, WHEN SHIPPED: "Pulvules Amytal and Acetyl-Salicylic Acid [or "Capsules Nembutal Sodium" or "Kapseals Benadryl Hydrochloride"] * * * Caution—To be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about April 15, 24, and 26, 1948, while the capsules were being held for sale after shipment in interstate commerce, the defendant caused a number of capsules of the articles to be removed from the bottles in which they had been shipped, to be repacked into boxes, and to be sold to various persons without a prescription, which acts of the defendant resulted in the capsules being misbranded. The repackaged capsules were labeled "Aspirin & Amytal," "Nembutal," and "Benadryl."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the labels of the repackaged capsules bore no statement containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they bore no statement of the quantity of the contents; Section 502 (d), the capsules of the articles other than the *benadryl hydrochloride capsules* were drugs for use by man and contained a chemical derivative of barbituric acid, which derivative has been found by the Administrator of the Federal Security Agency, after investigation, to be and by regulations designated as, habit forming, and the labels of the repackaged capsules of such articles failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming"; and, Section 502 (f) (1), the boxes containing the repackaged capsules bore no labeling containing directions for use.

DISPOSITION: May 23, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$500.

2696. Misbranding of Dr. Miller's Nosoil, Dr. Miller's Laxative Herbs, Dr. Miller's Deterg-All, Dr. Miller's Aspirin, Dr. Miller's Cascara Compound, and Dr. Miller's Laxative Pills. U. S. v. National Chemical Co. and William H. Dalton and Orland M. Dalton. Pleas of guilty. Fines of \$40 against company and \$17.50 against each individual, together with costs. (F. D. C. No. 25576. Sample Nos. 18760-K to 18762-K, incl., 18764-K, 18766-K, 18774-K.)

INFORMATION FILED: December 21, 1948, Southern District of Iowa, against the National Chemical Co., a corporation, Burlington, Iowa, and William H. Dalton, president, and Orland M. Dalton, secretary-treasurer.

ALLEGED SHIPMENT: Between the approximate dates of October 15, 1947, and January 3, 1948, from the State of Iowa into the State of Ohio.

LABEL, IN PART: "Dr. Miller's Nosoil For Nose and Throat," "Dr. Miller's Laxative Herbs," "Dr. Miller's * * * Deterg-All Mouth Wash & Throat Gargle," "Dr. Miller's * * * Aspirin," "Dr. Miller's Sugar Coated Cascara Compound," and "Dr. Miller's Laxative Pills."

NATURE OF CHARGE: *Dr. Miller's Nosoil*. Misbranding, Section 502 (a), certain statements in the labeling, which included an accompanying circular entitled "Dr. Miller's Family Remedies," were false and misleading since they represented and suggested that the article would be efficacious in the treatment and prevention of nose colds, hay fever, chronic sinus disease, and acute earache, whereas it would not be efficacious for such purposes; Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium, and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient since the ingredient phenol, which was declared on the label, was not declared by its common or usual name, carbolic acid; and, Section 502 (f) (2), the labeling failed to bear adequate warnings against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users since the article contained oil as a vehicle or base and was for use as nose drops, and its labeling failed to warn that frequent or excessive use of the preparation may cause injury to the lungs and that the preparation should not be used at all in infants and younger children except on competent advice.

Dr. Miller's Deterg-All. Misbranding, Section 502 (a), certain statements in the labeling, which included an accompanying circular entitled "Dr. Miller's Family Remedies," were false and misleading since they represented and suggested that the article would be efficacious in the treatment and prevention of sore mouth, pyorrhea, tonsillitis, and respiratory diseases, and in the treatment and prevention of many contagious diseases which find their way into the body by way of the mouth and throat, whereas it would not be efficacious for such purposes.

Dr. Miller's Aspirin. Misbranding, Section 502 (a), certain statements in the labeling, which included an accompanying circular entitled "Dr. Miller's Family Remedies," were false and misleading since they represented and suggested that the article would be efficacious in the treatment and prevention of neuritis, lumbago, sciatica, acute colds, tonsillitis and allied conditions, and any aching of the body of nerve and muscular origin, whereas it would not be efficacious for such purposes.

Dr. Miller's Cascara Compound. Misbranding, Section 502 (a), the label designation "Cascara Compound" was misleading since it represented and suggested that the laxative action of the article was derived solely from cascara, whereas the laxative action of the article was derived in part from other active laxative ingredients, aloin and podophyllin.

Dr. Miller's Laxative Pills. Misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium; it

was fabricated from two or more ingredients; and it contained strychnine and calomel; and the label of the article did not bear the name and quantity or proportion of strychnine contained in the article, a statement showing the substance from which the ingredient calomel was derived, and the fact that the ingredient was derived from mercury.

Further misbranding, Section 502 (b) (2), the labels on the *Dr. Miller's Nosoil*, the *Dr. Miller's Laxative Herbs*, and the *Dr. Miller's Aspirin* bore no statement of the quantity of the contents; the *Dr. Miller's Cascara Compound* and the *Dr. Miller's Laxative Pills* were not designated solely by names recognized in an official compendium, were fabricated from two or more ingredients, and contained the alkaloids atropine, hyoscyne, and hyoscyamine as constituents of belladonna; and the labels of the articles did not bear the name and quantity or proportion of such alkaloids nor in lieu thereof, the quantity or proportion of total alkaloids contained in the articles as constituents of belladonna.

Further misbranding, Section 502 (f) (2), the *Dr. Miller's Laxative Herbs*, the *Dr. Miller's Cascara Compound*, and the *Dr. Miller's Laxative Pills* were laxatives and the labeling failed to bear such adequate warnings against use in those pathological conditions where their use may be dangerous to health, in such manner and form as are necessary for the protection of users, since their labeling failed to bear warnings that they should not be used in the presence of abdominal pain (stomach ache, cramps, and colic), nausea, vomiting (stomach sickness), or other symptoms of appendicitis; and the labeling of such articles failed also to bear adequate warnings against unsafe dosage and duration of administration, since their labeling failed to warn that frequent or continued use of the articles might result in dependence on laxatives to move the bowels.

DISPOSITION: April 18, 1949. Pleas of guilty having been entered, the court imposed fines of \$40 against the company and \$17.50 against each individual, together with costs.

2697. Misbranding of Menestrex Capsules. U. S. v. 105 Bottles * * * (and 3 other seizure actions). (F. D. C. Nos. 24765, 25792, 25977, 25978. Sample Nos. 260-K, 999-K, 1317-K, 1318-K.)

LIBELS FILED: On or about May 12, October 26, and November 4 and 5, 1948, Northern District of Georgia.

ALLEGED SHIPMENT: On or about August 28 and September 5 and 6, 1947, and August 20 and September 8, 1948, by the Rex Laboratory, from Nashville, Tenn.

PRODUCT: 128 12-capsule bottles and 55 25-capsule bottles of *Menestrex Capsules* at Atlanta, Ga. Examination showed that each capsule of the product consisted essentially of 4 grains of quinine sulfate and 0.6 grain of potassium permanganate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of a portion of the product were false and misleading since the product was not effective in the treatment of scanty or functionally difficult menstruation: "Menestrex * * * For easing distress in scanty or functionally difficult menstruation * * * Start taking about 3 days before expected menstruation * * * Not for use during pregnancy"; and, Section 502 (f) (1), the labeling of the remainder of the product failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: June 15 and December 17, 1948. Default decrees of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2698. Adulteration of dextrose in isotonic solution of sodium chloride. U. S. v. 75 Flasks * * *. (F. D. C. No. 25156. Sample No. 54-K.)

LIBEL FILED: August 2, 1948, Eastern District of South Carolina.

ALLEGED SHIPMENT: On or about December 3, 1947, from Lakewood, Ohio.

PRODUCT: 75 flasks of *dextrose in isotonic solution of sodium chloride* at Columbia, S. C.

LABEL, IN PART: "Dextrose 10% W/V in Isotonic Solution of Sodium Chloride."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Dextrose and Sodium Chloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 28, 1948. Default decree of condemnation and destruction.

2699. Adulteration of ampuls of aminophylline and ampuls of sodium iodide and sodium salicylate with colchicine. U. S. v. 75 Cartons, etc. (F. D. C. No. 25354. Sample Nos. 10667-K, 10668-K.)

LIBEL FILED: August 12, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about July 7, 1948, by Bristol Laboratories, Inc., from Syracuse, N. Y.

PRODUCT: 75 cartons each containing 1 circular and 1 ampul of *aminophylline* and 75 cartons each containing 1 ampul of *sodium iodide and sodium salicylate with colchicine* at Elizabeth, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented, respectively, as "Aminophylline Injection," a drug the name of which is recognized in the United States Pharmacopoeia, and as "Sodium Salicylate and Iodide with Colchicine Ampuls," a drug the name of which is recognized in the National Formulary, and the quality and purity of the articles fell below the official standards since the articles were contaminated with undissolved material.

DISPOSITION: May 16, 1949. Default decree of condemnation and destruction.

2700. Adulteration of ampuls of iron cacodylate and thiamine. U. S. v. 250 Ampuls * * *. (F. D. C. No. 26257. Sample No. 28064-K.)

LIBEL FILED: January 24, 1949, District of New Mexico.

ALLEGED SHIPMENT: On or about October 19, 1948, from Kansas City, Mo.

PRODUCT: 250 ampuls of *iron cacodylate and thiamine* at Albuquerque, N. Mex.

LABEL, IN PART: "Iron Cacodylate and Thiamine 5 cc. * * * A sterile aqueous solution. For Intravenous Injection."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, namely, "Sterile solution For Intravenous Injection," since the article con-

*See also No. 2709.

tained undissolved material. An article represented for parenteral use should be substantially free of any undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: February 28, 1949. Default decree of condemnation.

2701. Adulteration and misbranding of sodium phenobarbital tablets. U. S. v. 7 Cartons * * * (and 1 other seizure action). (F. D. C. Nos. 24896, 25087. Sample Nos. 15049-K, 22908-K.)

LABELS FILED: June 23 and July 14, 1948, Northern District of Illinois and Middle District of Alabama.

ALLEGED SHIPMENT: On or about January 6 and 15, 1948, by Cole Laboratories, Inc., from Long Island City, N. Y.

PRODUCT: *Sodium phenobarbital tablets.* 7 cartons, each containing 24 bottles, at Hines, Ill., and 203 bottles at Montgomery, Ala. Examination showed that some of the bottles contained materially less than 1,000 entire tablets, together with broken and disintegrated tablets, and that some of the whole tablets contained less than 90 percent of the labeled amount of phenobarbital.

LABEL, IN PART: (Bottle) "1000 Hypodermic Tablets Each Tablet Contains 2 Grains (0.12 gm) Phenobarbital Sodium U. S. P. Distributed by Retort Pharmaceutical Co., Inc. Long Island City 1, New York."

NATURE OF CHARGE: Adulteration (portion), Section 501 (b), the article purported to be and was represented as "Sodium Phenobarbital Tablets," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard since a number of the whole tablets contained less than the declared amount of phenobarbital sodium.

Misbranding, Section 502 (a), the label statement "1000 * * * Tablets" was false and misleading since each bottle of the article contained materially fewer whole tablets than the declared number.

DISPOSITION: February 16, 1949. The Retort Pharmaceutical Co., Inc., having appeared as claimant and admitted the allegations of the libel, and the cases having been consolidated and removed to the Southern District of New York, judgment of condemnation was entered and the product was ordered released under bond for extraction of the phenobarbital, under the supervision of the Federal Security Agency.

2702. Adulteration of belladonna leaves. U. S. v. 3,642 Pounds * * *. (F. D. C. No. 24986. Sample No. 19167-K.)

LABEL FILED: June 30, 1948, Southern District of Indiana.

ALLEGED SHIPMENT: On or about February 6, 1948, by R. J. Prentiss & Co., Inc., from New York, N. Y.

PRODUCT: 3,642 pounds of *belladonna leaves* at Indianapolis, Ind. Examination showed that the product contained from 0.150 percent to 0.253 percent total alkaloids.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Belladonna Leaf," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard since it contained less than 0.3 percent of the alkaloids of belladonna leaf.

DISPOSITION: August 10, 1948. R. J. Prentiss & Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for use in medicated cigarettes.

On December 10, 1948, the decree was amended to provide for the labeling of the product as "Powdered belladonna leaves" and for the declaration on the label of the difference in the strength of the product from the official standard.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2703. Misbranding of Reiner's Reinol. U. S. v. Reiner Laboratories, Inc., and Paul J. Reiner. Pleas of guilty. Fine of \$250 against corporation; suspended sentence of 30 days in jail against individual. (F. D. C. No. 24262. Sample No. 83269-H.)

INFORMATION FILED: April 28, 1948, Southern District of Ohio, against Reiner Laboratories, Inc., a corporation, Cincinnati, Ohio, and Paul J. Reiner, president of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of March 20 and June 14, 1947, from the State of Ohio into the State of Indiana.

PRODUCT: Analysis disclosed that the product was a light-brown, water-alcohol solution with a wine-like odor, containing essentially potassium iodide, sodium salicylate, and sodium citrate.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying circulars entitled "Reiner's Reinol" and on an accompanying display easel were false and misleading since they represented and suggested that the article would be an adequate and effective treatment for rheumatism and arthritis; that it would help to eliminate acid from the system, remove many poisons from the body, alter the blood stream so as to increase the amount of poison it may carry from the body, relieve congestion caused by poisons lodging in the joints, and eliminate poisons by its action on the urinary tract, liver, nerves, and blood; and that it would exert a favorable influence over the causes of rheumatism and arthritis. The article would not be effective for the purposes represented.

Further misbranding, Section 502 (a), the statement on the easel "Comforting Relief from the Pains of Rheumatism Arthritis Neuritis Lumbago" was misleading since the statement represented and suggested that the article would favorably influence the course of rheumatism, arthritis, neuritis, and lumbago, whereas it would not favorably influence the course of such diseases, symptoms, and conditions.

DISPOSITION: February 21, 1949. Pleas of guilty having been entered, the court imposed a fine of \$250 against the corporation and sentenced the individual to serve 30 days in jail. The sentence against the individual was suspended, conditioned that he no longer engage in the sale of the product.

2704. Misbranding of Red Cell Caps. U. S. v. 224 Cartons * * *. (F. D. C. No. 25149. Sample No. 44065-K.)

LIBEL FILED: August 25, 1948, Western District of Kentucky.

*See also Nos. 2691, 2696, 2697, 2701.

ALLEGED SHIPMENT: On or about January 27 and February 6, 1948, by Evanston Labs., Inc., from Evanston, Ill.

PRODUCT: 224 cartons each containing 1 bottle of *Red Cell Caps* and a circular entitled "The Story of Red Cell Caps" at Louisville, Ky. Examination showed that the product consisted essentially of spray-dried blood and that the total iron content was 2.1 milligrams per capsule.

LABEL, IN PART: (Bottle) "Red Cell Caps 42-5 grain capsules."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. These statements represented and suggested that the article was effective as a blood building food and as a supplement to the diet, that it would maintain or produce beauty, health, and vibrant energy; and that it would regenerate the blood. The article would not be effective for such purposes.

DISPOSITION: December 1, 1948. Default decree of condemnation and destruction.

2705. Misbranding of Abbe Hamon Tea. U. S. v. 2 Packages, etc. (F. D. C. No. 25058. Sample Nos. 5181-K to 5188-K, incl., 5190-K, 5192-K, 5193-K, 5195-K to 5197-K, incl.)

LIBEL FILED: July 8, 1948, District of Massachusetts.

ALLEGED SHIPMENT: Between the approximate dates of January 9 and the month of June, 1948, by the Botanical and Marine Laboratories, from Manchester, N. H.

PRODUCT: 27 packages of various preparations of *Abbe Hamon Tea*, at Lowell, Mass.

LABEL, IN PART: "Tea No. 1. * * * Ingredients: Bark; Frangula. Leaves; Nettle, Eucalyptus, Bilberry, Geranium Robert. Nuts; Eucalyptus, Gall, Walnut Shuck. Roots; Bistort, Calamus. Grass; Knot Grass. Vehicle; Hazel leaves," "Tea No. 3. * * * Ingredients: Bark; Frangula. Leaves; Horse Tail, Ulmaire, Woodruff, Maize Stigma. Vehicle; Hazel leaves," "Tea No. 11. * * * Ingredients: Leaves; Box. Roots; Couchgrass, Patience dock, Liquorice. Seaweed; Fucus Vesiculosus. Vehicle; Hazel leaves," "Tea No. 14. * * * Ingredients: Bark; Oak. Leaves; Woodruff, Shepherds purse. Roots; Bistort Liquorice. Vehicle; Hazel leaves," "Tea No. 16. * * * Ingredients: Flowers; Genista. Leaves; Woodruff, Centaury, Gratiola. Roots; Burdock, Thistle Rolland, Liquorice. Seeds; Carrot. Vehicle; Hazel leaves," "Tea No. 18. * * * Ingredients: Leaves; Bilberry, Geranium Robert, Violet, Peppermint, Shepherds Purse. Roots; Inula. Vehicle; Hazel leaves," "Tea No. 6. * * * Ingredients: Flowers; Lime, Elder, Poppy Feverfew. Leaves; Oak Mistletoe. Roots; Nenuphar, Valerian. Vehicle; Hazel leaves," "Tea No. 20. * * * (Leaves; Ash, hysop, mint, hazel nut, field horsetail, green of the meadow)," "Tea No. 4. * * * Ingredients: Bark; Oak. Leaves; Catmint, Centaury, Walnut; Roots; Gentian, Calamus. Vehicle; Hazel leaves," "Tea No. 7. * * * Constituent Herbs Anchusa Officinalis—Papaver Rhoeas—Viscum Album—Coryllus Avellana—Sambucus Nigra," "Tea No. 8. * * * Ingredients: Bark; Frangula. Leaves; Artemisia, Wormwood, White Horehound. Seeds; Parsley. Vehicle; Hazel leaves," "Tea No. 10. * * * (Barks; oak, willow. Leaves; Mint, hazelnut. Berry; Whortleberry. Nut; Gall. Root; snakeweed)," "Tea No. 12. * * * Ingredients: Bark; Frangula. Flower; Scabiosa. Leaves; Chicory, Box Centaury, St. Johns Wort. Roots; Fumitory, Couchgrass; Gentian. Vehicle; Hazel leaves," and

"Tea No. 13. * * * Ingredients: Flowers; Lavender. Origan. Marjoram. Seeds; Angelica, Anise, Caraway, Coriander, Fennel. Roots; Angelica. Vehicle; Hazel leaves."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading. The statements represented and suggested that the articles were effective in the treatment of the following diseases, symptoms, and conditions; (No. 1 Tea) diabetes; (No. 3 Tea) rheumatism, gout, sciatica, arthritis; (No. 11 Tea) obesity, paralysis, goiter, arteriosclerosis; (No. 14 Tea) bad circulation, varicose veins, piles, congestion, phlebitis, hemorrhage; (No. 16 Tea) heart disease, kidneys, liver, and urinary organs; (No. 18 Tea) ulcers of the stomach and the intestines; (No. 6 Tea) nervousness, epilepsy, St. Vitus' dance, hysteria, neurasthenia; (No. 20 Tea) Spring and Autumn conditions, infectious disease, poor appetite; (No. 4 Tea) "aneamia" and critical age; (No. 7 Tea) whooping cough and all respiratory troubles in children; (No. 8 Tea) menstrual irregularity, insufficiency, and menopause; (No. 10 Tea) diarrhea and enteritis; (No. 12 Tea) pimples, acne, and vitiated blood; and (No. 13 Tea) stomach complaints. The articles were not effective in the treatment of such diseases, symptoms, and conditions.

DISPOSITION: September 27, 1948. Default decree of condemnation and destruction.

2706. Misbranding of Prostall. U. S. v. 10 Bottles, etc. (F. D. C. No. 26382. Sample No. 32509-K.)

LIBEL FILED: January 13, 1949, Northern District of California.

ALLEGED SHIPMENT: By Douglas Laboratories, Inc., from Boston, Mass. The product was shipped on or about November 12, 1948, and a number of leaflets were shipped on or about October 29, 1948.

PRODUCT: 10 100-capsule bottles of *Prostall* at San Francisco, Calif., together with a number of leaflets entitled "The Story of Prostall." In addition a placard which was prepared by the consignee was displayed with the product. The shipper, however, had suggested the wording to be used on the placard in a letter dated February 27, 1947. Analysis showed that the product consisted of amino acids.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in the leaflets were false and misleading since they represented and suggested that the article was effective in the relief of pain and prostate hypertrophy, whereas the article was not effective for such purposes. The article was misbranded in this respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), certain statements on the placard were false and misleading since they represented and suggested that the article was effective in the relief of urinary frequency and nocturia, whereas the article was not effective for such purposes. The article was misbranded in the latter respect while held for sale after shipment in interstate commerce.

DISPOSITION: March 1, 1949. Default decree of condemnation. The product was delivered to the Food and Drug Administration.

2707. Misbranding of Eskimo Vibrator. U. S. v. Bersted Manufacturing Co. Plea of nolo contendere. Fine of \$100 and costs. (F. D. C. No. 26695. Sample Nos. 20728-K, 31625-K.)

INFORMATION FILED: May 9, 1949, Northern District of Ohio, against the Bersted Manufacturing Co., a corporation, Fostoria, Ohio.

ALLEGED SHIPMENT: On or about August 24 and September 7, 1948, from the State of Ohio into the States of Nebraska and California.

PRODUCT: Examination disclosed that the product was an electric vibrator with various attachments, consisting of one cup applicator attached to the device, one sponge rubber applicator, one solid applicator, and one scalp applicator.

LABEL, IN PART: "Eskimo Two Speed Vibrator."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the device and in an accompanying circular entitled "Vibrator Two Speeds Vibrate Your Way To Health and Beauty" were false and misleading. These statements represented and suggested that the device would be efficacious in the treatment of sore muscles, headaches, rheumatism, and constipation; that it would cause curative action by increasing the circulation of the blood and stimulating the nerves; that it would be efficacious in the treatment of neuralgia, blackheads, obesity, insomnia, nervousness, double chin, wrinkles, and sagging muscles; and that it would vibrate the user to health and beauty. The device would not be efficacious for such purposes.

DISPOSITION: May 24, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$100 and costs.

2708. Misbranding of Eskimo Vibrator. U. S. v. 94 Devices * * *. (F. D. C. No. 26405. Sample No. 25568-K.)

LABEL FILED: January 20, 1949, District of Minnesota.

ALLEGED SHIPMENT: On or about November 20, 1948, by the Bersted Manufacturing Co., from Fostoria, Ohio.

PRODUCT: 94 vibrators at Minneapolis, Minn. Examination showed that the device was an electric vibrator fitted with several attachments.

LABEL, IN PART: "Eskimo Two Speed Vibrator."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the device and in a circular attached to the device were false and misleading. The nature of the false and misleading statements is set forth in the preceding notice of judgment, No. 2707.

DISPOSITION: June 21, 1949. The Bersted Manufacturing Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the device was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

2709. Adulteration and misbranding of Annel Hog-Liquid and General Hog-Liquid. U. S. v. General Veterinary Co. and Carl R. Kleesick. Pleas of nolo contendere. Fine of \$40 and costs against company and \$10 against individual. (F. D. C. No. 25585. Sample Nos. 25213-K, 25222-K.)

INFORMATION FILED: January 12, 1949, District of Nebraska, against the General Veterinary Co., a partnership, Omaha, Nebr., and Carl R. Kleesick, a partner in the partnership.

ALLEGED SHIPMENT: On or about March 25 and April 23, 1948, from the State of Nebraska into the States of Minnesota and Iowa.

LABEL, IN PART: "Annel Hog-Liquid [or "General Hog-Liquid"] * * * Ingredients Calcium Phosphate Breechwood Creosote Potassium Iodide Ex-

tract of Glycyrrhiza Sodium Hydroxide Copper Sulphate Creosote U. S. P. Water 19.5%. Extract of Nux Vomica."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles differed from that which they were represented to possess. The articles were represented to contain 59.5 percent of solution of potassium arsenite, and one quart of the articles was represented to contain 60 grains of arsenic. The articles contained more than 59.5 percent of solution of potassium arsenite, and one quart contained more than 60 grains of arsenic.

Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading. These statements represented and suggested that the articles contained 59.5 percent of solution of potassium arsenite; that one quart contained 60 grains of arsenic; and that when used as directed, the articles would be efficacious in overcoming an excess acid condition of the stomach in hogs and in the treatment in hogs of intestinal infection and diarrheas associated with hyperacidity. The articles contained more solution of potassium arsenite and more arsenic than represented, and they would not be efficacious for the purposes represented.

DISPOSITION: March 3, 1949. Pleas of nolo contendere having been entered, the court imposed a fine of \$40 and costs against the company and \$10 against the individual.

2710. Misbranding of C. L. C. Mineral Supplement. U. S. v. 5 Bags, etc. (F. D. C. No. 24768. Sample No. 12020-K.)

LIBEL FILED: May 10, 1948, Middle District of Pennsylvania; amended libel filed July 8, 1948.

ALLEGED SHIPMENT: By C. L. C. Minerals, Inc., from Hagerstown, Md. The product was shipped on or about March 22, 1948, and a number of leaflets were shipped on or about February 2, 1948.

PRODUCT: 5 100-pound bags of *C. L. C. Mineral Supplement* at Belleville, Pa., together with a number of leaflets entitled "C. L. C. Minerals The Answer to your mineral problems." Examination showed that the product consisted of approximately 77 percent ash and 1½ percent acid insoluble ash.

LABEL, IN PART: "C. L. C. Mineral Supplement * * * Manufactured by Central Laboratories Hagerstown, Md."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets were false and misleading since they represented and suggested that the article was effective to build up the vital organs and prevent diseases common and extensive among domestic animals and fowls; and to regulate digestive troubles, improve feathering, increase appetite, prevent leg weakness, make for faster growth, increase hatchability of eggs, produce healthy chicks, increase egg production, prolong the laying life of the hen, prevent cannibalism or feather picking, maintain body and health, keep the heavy milker in top condition, increase milk flow and butterfat in cows, help to produce a healthy calf a year, overcome breeding difficulties if caused by mineral shortage, help to prevent abortion caused mostly by mineral shortage (not contagious abortion), help to prevent goiter and depraved and unnatural appetite, save feed, build stronger, heavier bones, give better distribution of fat throughout the meat, keep steers from getting stuck on full feed, save about 25 percent pasture, make the stock consume more water, increase percentage of kill weight, give a better finish or bloom, have steers ready for market in less than eighteen

months if C. L. C. was fed daily, keep stock in perfect health and help to prevent worms, produce stronger lambs and more lambs, make lambing easier, produce better finish and more weight, increase quality of wool, develop a large dense-boned skeleton, prevent swollen joints, make sows nurse their pigs well, prevent sows going down in the back, stop rooting, prevent sows from eating their pigs, and produce more pounds of pork with less feed. The article was not effective for such purposes.

DISPOSITION: March 23, 1949. C. L. C. Minerals, Inc., having appeared as claimant and subsequently having consented to a decree providing for disposition in accordance with the Act, judgment of condemnation was entered and the product was ordered destroyed.

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Miller's, Dr., Nosoil, Dr. Miller's		Vitamin preparation	2700
Laxative Herbs, Dr. Miller's		Women's disorders, remedies for	2697

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N. J. No.		N. J. No.
Bersted Mfg. Co.:		Central Laboratories:	
Eskimo Vibrator	2707, 2708	C. L. C. Mineral Supplement	2710
Botanical and Marine Laborato-		Cole Laboratories, Inc.:	
ries:		sodium phenobarbital tablets	2701
Abbe Hamon Tea	2705	Dalton, O. M., and W. H.:	
Bristol Laboratories, Inc.:		Dr. Miller's Nosoil, Dr. Miller's	
ampuls of aminophylline and		Laxative Herbs, Dr. Miller's	
ampuls of sodium iodide and		Deterg-All, Dr. Miller's As-	
sodium salicylate with col-		pirin, Dr. Miller's Cascara	
chicine	2699	Compound, and Dr. Miller's	
C. L. C. Minerals, Inc.:		Laxative Pills	2696
C. L. C. Mineral Supplement	2710		

¹ (2691) Prosecution contested.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS—Continued

	N. J. No.		N. J. No.
Douglas Laboratories, Inc.:		National Chemical Co.:	
Prostall.....	2706	Dr. Miller's Nosoil, Dr. Miller's	
Evanston Labs., Inc.:		Laxative Herbs, Dr. Miller's	
Red Cell Caps.....	2704	Deterg-All, Dr. Miller's As-	
General Veterinary Co.:		pirin, Dr. Miller's Cascara	
Annel Hog-Liquid and General		Compound, and Dr. Miller's	
Hog-Liquid.....	2709	Laxative Pills.....	2696
Gresham, R. S.:		Pillers, J. M.:	
benzedrine sulfate tablets and		seconal sodium pulvules.....	2694
thyroid tablets.....	2692	Pillers, J. M., & Son City Drug	
Hilsher, J. M.:		Store. See Pillers, J. M.	
seconal pulvules.....	2693	Prentiss, R. J., & Co., Inc.:	
Keene Pharmacal Co.:		belladonna leaves.....	2702
seconal pulvules.....	2693	Ray's Pharmacy:	
Klesick, C. R.:		benzedrine sulfate tablets and	
Annel Hog-Liquid and General		thyroid tablets.....	2692
Hog-Liquid.....	2709	Reason, E. D.:	
Lilly, Eli, & Co.:		Penicillin Oil Vehicle with Wax	
seconal sodium pulvules.....	2693	and Penicillin Oil Vehicle.... ¹	2691
Lloyd, H. A.:		Reiner, P. J.:	
seconal pulvules.....	2693	Reiner's Reinol.....	2703
Lloyd's, Harold, Prescriptions.		Reiner Laboratories, Inc.:	
See Keene Pharmacal Co.		Reiner's Reinol.....	2703
Miller, R. C.:		Retort Pharmaceutical Co., Inc.:	
amyltal and acetyl-salicylic acid		sodium phenobarbital tablets..	2701
capsules, nembutal sodium		Rex Laboratory:	
capsules, and benadryl hy-		Menestrex Capsules.....	2697
drochloride capsules.....	2695	Stogsdill, P. L.:	
Miller, E. S., Laboratories, Inc.:		seconal pulvules.....	2693
Penicillin Oil Vehicle with Wax		Western, B. B.:	
and Penicillin Oil Vehicle.... ¹	2691	benzedrine sulfate tablets and	
Miller's Rexal Drug Store. See		thyroid tablets.....	2692
Miller, R. C.			

¹ (2691) Prosecution contested.

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2711-2730

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., January 3, 1950.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2711. Misbranding of Foille Emulsion. U. S. v. 77 Bottles, etc. (F. D. C. No. 26960. Sample Nos. 53355-K to 53358-K, incl.)

LABEL FILED: March 28, 1949, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about February 9 and July 15, 1948, and January 21 and March 15, 1949, by the Carbisulphoil Co., from Dallas, Tex.

PRODUCT: 2 1-pint bottles, 1 1-gallon bottle, and 60 1½-ounce bottles of *Foille Emulsion* at New Orleans, La., together with 14 sample kits, each containing one bottle of *Foille Emulsion*, one tube of *Foille Ointment*, and various pieces of literature.

*For new drug shipped without effective application, see No. 2713; cosmetics, subject to the drug provisions of the Act, Nos. 2726, 2727.

LABEL, IN PART: (Bottle) "Foille Emulsion A Protective Dressing. Analgesic-Antiseptic. Ingredients: Benzocaine, Carbolic Acid (Less than 2 Percent), Calcium Oleate, Calcium and Potassium Iodides, Oxyquinoline Base, Calcium Thiosulfate and sulphur in a Vegetable Oil Base * * * Directions: Apply liberally to gauze compress or directly to wound area."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and methods and duration of administration and application, in such manner and form as are necessary for the protection of users. The article contained carbolic acid, and its labeling failed to warn against application to large areas of the body, and against bandaging the fingers and toes to which the article was applied.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely (bottle label), "Apply liberally to gauze compress or directly to wound area" and (brochure entitled "Burns") "Dressing saturated with Foille Emulsion should be applied directly to the wound and the dressing kept moist with Foille. * * * In some cases, * * * it may be appropriate to continue with the original dressings for a longer period of time by frequently saturating them with Foille in order to keep the area moist, soft, and pliable. Such treatment may be continued either with or without changing the dressings until healing is complete or until conditions are satisfactory for grafting. * * * Foille Emulsion is applied directly to the injured areas either by pouring, spreading with a camel's-hair brush or spraying with a special atomizer. Under open, cradle treatment method, Foille Emulsion is reapplied at regular intervals, either with saturated compresses or direct without benefit of dressings as indicated above."

DISPOSITION: April 28, 1949. Default decree of condemnation and destruction.

2712. Misbranding of Foille Emulsion. U. S. v. 9 Bottles, etc. (F. D. C. No. 26953. Sample Nos. 53430-K, 53431-K.)

LABEL FILED: March 24, 1949, Northern District of Alabama.

ALLEGED SHIPMENT: On or about January 17, February 22, and March 14, 1949, by the Carbisulphol Co., from Dallas, Tex.

PRODUCT: 9 16-ounce bottles, 15 4-ounce bottles, 279 1½-ounce bottles, 2 1-gallon bottles, and 6 1-quart bottles of *Foille Emulsion* at Birmingham, Ala., together with 2 brochures entitled "Burns" which were delivered by a representative of the shipper.

LABEL, IN PART: (Bottle) "Foille Emulsion A Protective Dressing. Analgesic-Antiseptic. Ingredients: Benzocaine, Carbolic Acid (Less than 2 Percent), Calcium Oleate, Calcium Thiosulfate and sulphur in a Vegetable Oil Base * * * Directions: Apply liberally to gauze compress or directly to wound area."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the article contained carbolic acid, and its labeling failed to warn against application to large areas of the body, and against bandaging the fingers and toes to which the article was applied.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely (bottle label), "Apply

liberally to gauze compress or directly to wound area" and (brochure entitled "Burns") "Dressing saturated with Foille Emulsion should be applied directly to the wound and the dressing kept moist with Foille. * * * In some cases, * * * it may be appropriate to continue with the original dressings for a longer period of time by frequently saturating them with Foille in order to keep the area moist, soft and pliable. Such treatment may be continued either with or without changing the dressings until healing is complete or until conditions are satisfactory for grafting. * * * Foille Emulsion is applied directly to the injured areas either by pouring, spreading with a camel's-hair brush or spraying with a special atomizer. Under open, cradle treatment method, Foille Emulsion is reapplied at regular intervals, either with saturated compresses or direct without benefit of dressings as indicated above."

DISPOSITION: April 25, 1949. Default decree of condemnation and destruction.

2713. Misbranding of syrup urethane. U. S. v. 9 Bottles * * *. (F. D. C. No. 26649. Sample No. 9128-K.)

LIBEL FILED: March 15, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about January 5, 1949, by Marvin R. Thompson, Inc., from Stamford, Conn.

PRODUCT: 9 16-ounce bottles of *syrup urethane* at Hackensack, N. J.

LABEL, IN PART: "Syrup Urethane—M. R. T. * * * Each teaspoonful (5-cc) contains urethane 4 Grs. in a flavored syrup base."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in its labeling, namely, "1 teaspoonful every 3 or 4 hours," since the administration every 3 or 4 hours of 1 teaspoonful of the article containing the stated amount of urethane is capable of causing leucopenia.

Violation of Section 505, the article was a drug which should not have been introduced into interstate commerce, since it was a new drug within the meaning of the law and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: April 25, 1949. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for experimental purposes.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2714. Misbranding of yeast capsules. U. S. v. 129 Boxes * * *. (F. D. C. No. 26618. Sample No. 27878-K.)

LIBEL FILED: February 24, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about December 30, 1948, from Detroit, Mich.

PRODUCT: 129 boxes each containing 50 *yeast capsules* at St. Louis, Mo. The product was offered orally by its distributor, Albert Christy, during the course of lectures delivered by him at St. Louis on January 11, 1949, for constipation and to introduce flora into the intestines, to remove pin worms and hook worms

*See also Nos. 2711, 2712.

from the intestines, and to supply elements needed by the body to keep itself well.

LABEL, IN PART: "Albert Christy's 'G' Strain Yeast Capsules 7½ minim in liquid form A food supplement * * * Directions: as a dietary supplement, three capsules per day, one with each meal."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: March 24, 1949. Default decree of condemnation and destruction.

2715. Misbranding of Vita-Ray Compound and Vita-Ray Inhalator. U. S. v. 225 Bottles, etc. (F. D. C. No. 26610. Sample Nos. 4109-K, 4110-K.)

LIBEL FILED: February 19, 1949, District of Massachusetts.

ALLEGED SHIPMENT: On or about January 20, 1949, from Chicago, Ill.

PRODUCT: 225 1-ounce bottles and 99 4-ounce bottles of *Vita-Ray Compound* and 85 *Vita-Ray Inhalators* at Boston, Mass. The article was in possession of Herman Mendelsohn, lecturer.

LABEL, IN PART: (Bottle) "Nu-Life (Brand) Vita-Ray Compound Active Ingredients Eucalyptus Oil, Menthol, Thymol, Camphor, Peppermint Oil"; (inhaler) "Nu-Life Vita-Ray Inhalator."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on placards displayed where the articles were being offered for sale were false and misleading since the articles were not an effective treatment of the conditions stated "Guaranteed Relief Vita Ray for Sinus Colds" and "Relief for Rheumatism and Arthritis"; and, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use for the purposes for which the articles were intended. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 4, 1949. Default decree of condemnation and destruction.

2716. Misbranding of Electric Insoles. U. S. v. 36 Pairs * * *. (F. D. C. No. 26631. Sample No. 14190-K.)

LIBEL FILED: March 4, 1949, Northern District of Indiana.

ALLEGED SHIPMENT: During the months of November 1947, and August 1948, by Jacob S. Coxey, Sr., from Massillon, Ohio.

PRODUCT: 36 pairs of *Electric Insoles* at Tremont, Ind., together with a dated letter of September 1, 1948, from the shipper of the devices. The devices consisted of one copper and one zinc plate to be worn in the heels of one's shoes.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements in the letter of September 1, 1948, "He should wear a pair of Electric Insoles as they will make the Blood flow freely and aid him in walking" were false and misleading since the device was not effective in the treatment of the conditions stated; and, Section 502 (f) (1), the labeling failed to bear adequate directions for use for the purposes for which the device was intended.

DISPOSITION: May 11, 1949. Default decree of condemnation and destruction.

2717. Misbranding of Thermapax Health Applicator. U. S. v. 6 Devices * * *.
(F. D. C. No. 26672. Sample No. 53117-K.)

LIBEL FILED: March 2, 1949, Northern District of Alabama.

ALLEGED SHIPMENT: On or about February 26, 1949, by Rhys Davies, from Fort Wayne, Ind.

PRODUCT: 6 devices known as *Thermapax Health Applicator* at Birmingham, Ala. The device consisted of an electric heating coil in a metal helmet.

LABEL, IN PART: "Thermo-Magno-Ray Thermapax Health Applicator."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Health Applicator" represented and suggested that the article was beneficial in regaining and maintaining health, whereas the article was not beneficial for such purposes; and, Section 502 (f) (1), the labeling of the article bore no directions for use.

DISPOSITION: April 25, 1949. Rhys Davies, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the devices were ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2718. Adulteration of solution of thiamine hydrochloride. U. S. v. 94 Vials
* * *. (F. D. C. No. 25683. Sample Nos. 43456-K, 43457-K.)

LIBEL FILED: October 15, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about August 2, 1948, by the Dabney Pharmacal Co., from Louisville, Ky.

PRODUCT: 94 30-cc. vials of solution of *thiamine hydrochloride* at Chicago, Ill.

LABEL, IN PART: "Solution Thiamine Hydrochloride For Intramuscular or Subcutaneous use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine-Hydrochloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since the article was contaminated with undissolved material.

DISPOSITION: March 17, 1949. Default decree of condemnation and destruction.

2719. Adulteration and misbranding of chorionic gonadotropin. U. S. v. 60 vials
* * *. (F. D. C. No. 26584. Sample No. 11266-K.)

LIBEL FILED: March 3, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about October 28, 1948, by Associated Ross-Good Laboratories, Inc., from Philadelphia, Pa.

PRODUCT: 60 10-cc. vials of *chorionic gonadotropin* at New York, N. Y. The article was shipped unlabeled and was labeled by the consignee.

LABEL, IN PART: "Sterile Chorionic Gonadotropin for Intramuscular Injection."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since it was for parenteral administration and was not sterile.

*See also No. 2729.

Misbranding, Section 502 (a), the label statement "sterile" was false and misleading as applied to an article that was not sterile but was contaminated with viable micro-organisms. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: April 19, 1949. Default decree of condemnation and destruction.

2720. Adulteration and misbranding of estrogenic substance. U. S. v. 48 Vials

* * *. (F. D. C. No. 26613. Sample Nos. 11258-K, 11271-K.)

LIBEL FILED: February 24, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about November 24, 1948, by Estro Chemical Co., Inc., from New York, N. Y.

PRODUCT: 48 10-cc. vials of *estrogenic substance* at Union City, N. J. The product was shipped under a label identical to that set forth below, except that the brand name "Aqua-Gyne" and the name and address of the manufacturer, the Estro Chemical Co., appeared thereon in place of the brand name "Aquacrine" and the name and address of the distributor, the Endocrine Co.

LABEL, IN PART: "Aquacrine Aqueous Estrogenic Substance * * * Distributed By Endocrine Company, Union City, N. J."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 97 percent of the amount of estrone necessary to produce a potency of 20,000 International Units per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc * * * contains * * * Estrogenic Substances (predominantly Estrone) * * * (Ketosteroids as Estrone, approximately 97% by potency). * * * equivalent to 20,000 I. U. (assayed in terms of Estrone)" was false and misleading as applied to the article, which contained materially less than 97 percent of the amount of estrone necessary to produce a potency of 20,000 International Units per cubic centimeter.

DISPOSITION: May 2, 1949. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for experimental purposes.

2721. Adulteration and misbranding of chloro-iodo-hydroxy-quinoline. U. S. v.

1 Drum * * *. (F. D. C. No. 26938. Sample No. 11345-K.)

LIBEL FILED: March 21, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about May 25, 1948, by the R. S. A. Corp., from Ardsley, N. Y.

PRODUCT: 1 25-pound drum of *chloro-iodo-hydroxy-quinoline* at South Hackensack, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), di-iodo-hydroxy-quinoline had been substituted in part for chloro-iodo-hydroxy-quinoline.

Misbranding, Section 502 (a), the name "Chloro-Iodo-Hydroxyquinoline" was false and misleading as applied to the article, which consisted of a mixture of chloro-iodo-hydroxy-quinoline and di-iodo-hydroxy-quinoline.

DISPOSITION: May 2, 1949. Default decree of condemnation. One pound of the product was ordered delivered to the Food and Drug Administration, for experimental purposes, and the remainder was ordered destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2722. Misbranding of Lemel. U. S. v. 300 Dozen Packages * * *. (F. D. C. No. 26006. Sample No. 2748-K.)

LABEL FILED: November 4, 1948, District of Columbia.

ALLEGED SHIPMENT: On or about October 28, 1948, by the Serutan Co., from Newark, N. J.

PRODUCT: 300 dozen packages of *Lemel* at Washington, D. C.

LABEL, IN PART: (Package) "Lemel 20 Packets Each Packet Contains Vitamin C Equal to 7 Lemons (Av.) Ingredients: Dextrose, lemon powder, oil of lemon, oil of lime, potassium bitartrate and tartaric acid (from grapes), potassium citrate, ascorbic acid, thiamin hydrochloride, riboflavin, niacin, niacinamide, potassium phosphate, magnesium carbonate, calcium carbonate. Lo-Calory Food Corp., New York, N. Y. Each Lemel Packet Contains: Vitamin C . . . 150 mgs. (5 MDR), Vitamin B₁ . . . 5 mgs. (5 MDR), Riboflavin . . . 2 mgs. (1 MDR), Niacin . . . 25 mgs.* Niacinamide . . . 25 mgs.* MDR-Minimum Daily Requirement. *MDR not established."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in a leaflet enclosed in each package of the product were false and misleading: "Lemonade has long been used in colds, grippe and flu. Many who suffer from joint aches and pains are accustomed to taking the juice of 1 or more lemons as a morning drink. Today, in Lemel you can get the Vitamin C value of the juice of 7 Average Lemons * * * Use Lemel regularly and faithfully." The statements represented and suggested that the article was effective in the treatment of colds, grippe, flu, and joint aches and pains. The article was not effective in the treatment of such diseases, symptoms, and conditions.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 14293.

DISPOSITION: December 15, 1948. Lo-Calory Food Corp., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Food and Drug Administration.

2723. Misbranding of lemon juice. U. S. v. 22 Cases * * * (and 1 other seizure action). (F. D. C. Nos. 26092, 26093. Sample Nos. 18293-K, 18294-K.)

LABELS FILED: November 24, 1948, Northern District of Ohio.

ALLEGED SHIPMENT: On or about September 1, 1948, by the Puritan Company of America, from Chicago, Ill.

PRODUCT: 77 cases, each containing 24 1-pint bottles, of *lemon juice* at Cleveland, Ohio.

LABEL, IN PART: "Realemon Brand 100% Real California Lemon Juice."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "For Health and Regularity * * * For Fighting or Breaking Colds" were false and misleading since use of the product would not promote health and regularity, and the product would not be effective in the treatment of colds.

*See also Nos. 2715-2717, 2719-2721.

The product was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods.

DISPOSITION: January 12, 1949. Default decrees of condemnation and destruction.

2724. Misbranding of Rybutol Gelucaps. U. S. v. 124 Dozen Bottles, etc.
(F. D. C. No. 26636. Sample No. 51252-K.)

LIBEL FILED: March 7, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: By the Vitamin Corporation of America, from Newark, N. J. The product was shipped on or about January 11, 1949, and the labeling of the article, with the exception of certain newspaper clippings, was shipped on or about January 10 and February 12, 1949.

PRODUCT: 70 dozen bottles, each containing 100 capsules, and 54 dozen bottles, each containing 50 capsules, of *Rybutol Gelucaps* at Cincinnati, Ohio, in the possession of the Dow Drug Co. Warehouse, together with a number of leaflets entitled "Ask Your Doctor" and a number of Cincinnati newspaper clippings entitled "Why does your Doctor Prescribe Rybutol?" The newspaper clippings were displayed with the product in the retail stores of the Dow Drug Co. Some of the clippings were pasted in the windows of the stores or were used as streamers, hanging from a wire in the rear of the stores in close proximity to the goods.

LIBEL, IN PART: "Rybutol High Blend Natural Vitamin B Complex. Each Gelucap Contains the Whole Natural Vitamin B Complex Fortified."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the newspaper clippings were misleading. These statements represented and suggested that the article was effective to correct and prevent nervousness, mental depression, atrophy, fatigue, loss of appetite, allergies, dental decay, gum infections, excessive weight, anemias, paleness of the skin, loss of energy, palpitation, run-down feeling, listlessness, improper food assimilation, faulty elimination, and birth of anemic infants. The article was not effective for such purposes. The article was misbranded while held for sale after shipment in interstate commerce by reason of the above statements in its labeling.

Further misbranding, Section 502 (a), the statement "Hy-Blend Natural Vitamin B Complex" appearing on the label of the article, in a leaflet entitled "Ask Your Doctor," and in the newspaper clippings, was false and misleading as applied to an article which was not a high potency natural vitamin B complex but a mixture of some of the members of the vitamin B complex in synthetic form, an iron salt, vitamin C, and nutritionally inconsequential amounts of natural sources of the B complex.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: March 14, 1949. The Vitamin Corporation of America, claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

2725. Misbranding of S-V-S^x Vitamin Tablets. U. S. v. 26 Boxes * * *.
(F. D. C. No. 26655. Sample No. 40314-K.)

LIBEL FILED: March 14, 1949, District of Maryland.

ALLEGED SHIPMENT: On or about July 23, 1948, by the Pell-Ma Medicine Co., from Los Angeles, Calif.

PRODUCT: 26 boxes of *S-V-S^x Vitamin Tablets* at Baltimore, Md.

LABEL, IN PART: (Box) "*S-V-S^x Pell-Ma Brand * * * Super Vita Sparks X Vitamin B₁, B Complex and Iron Tonic 30 Tablets.*"

NATURE OF CHARGE: Misbranding, Section 502 (a), the conspicuous statement in the leaflet enclosed in each box, namely, "*The Aristocrat of Glandular Products,*" and the supplementary statement, "*With Hormones and Gland Extracts,*" were false and misleading since the article possessed no physiologic or therapeutic properties due to its content of hormones or gland extracts, and the false and misleading impression created by such representations was not exonerated by the less conspicuous labeling statement "*Inactive Ingredients Androgenic Substance, from Sterols, 10 Capon Units Orchic Substance (Testes) 85.0 Mg. Prostate Gland Substance 85.0 Mg. * * * There is no scientific evidence to indicate that the Androgenic, Orchic and Prostate substances in this product have therapeutic or physiological activity.*"

DISPOSITION: April 19, 1949. Default decree of condemnation and destruction.

2726. Misbranding of estrogenic hormone cream. U. S. v. 176 Jars, etc. (F. D. C. No. 26641. Sample No. 2790-K.)

LABEL FILED: March 9, 1949, District of Columbia.

ALLEGED SHIPMENT: On or about October 30, 1948, and January 10, 1949, by the Everyyoung Cosmetic Co., from New York, N. Y.

PRODUCT: 176 3-ounce jars and 138 1-ounce jars of *estrogenic hormone cream* at Washington, D. C., together with a number of leaflets entitled "*This Precious Cream.*"

LABEL, IN PART: "*The Second Youth Estrogenic Hormone Cream One ounce of this Hormone Cream contains 7,500 Units of Natural Estrogenic Hormones.*"

NATURE OF CHARGE: Misbranding, Section 502 (a), the picture of a young woman on the jar label and the following statements on the label and in the leaflet were false and misleading since the article was not effective to accomplish the results stated and implied: (Jar label) "*The Second Youth * * * Everyyoung,*" and (leaflet) "*Helps to keep your youthful appearance * * * The Second Youth * * * Everyyoung * * * Look Younger and More Attractive Day by Day * * * It helps to stimulate undernourished skin; it helps to erase eyelines, large pores and skin impurities, brings back fresh and youthful glow to faded face and neck.*"

DISPOSITION: April 5, 1949. Default decree of condemnation and destruction.

2727. Misbranding of Alapex. U. S. v. 11 Bottles, etc. (F. D. C. No. 26624. Sample No. 46579-K.)

LABEL FILED: February 28, 1949, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 30, 1948, and January 6 and February 11, 1949, by Algo Products, Inc., from Cleveland, Ohio.

PRODUCT: 11 1-pint bottles and 31 4-ounce bottles of *Alapex* at Pittsburgh, Pa., together with a number of display cards entitled "*Ask About Alapex*" and circulars entitled "*Lets be Honest About Checking Falling Hair, Making Hair Grow.*" Analysis showed that the product consisted essentially of salicylic acid, thymol, and resorcinol monoacetate dissolved in alcohol and water.

LABEL, IN PART: "*Alapex for the Scalp.*"

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the display cards and in the circulars were false and misleading since they

represented and suggested that the article was effective in the treatment of falling hair, baldness, and dandruff. The article was not effective for such purposes.

DISPOSITION: March 30, 1949. Default decree of condemnation and destruction.

2728. Misbranding of Magnetic Teething Necklace. U. S. v. 5 Dozen * * *
(F. D. C. No. 26429. Sample No. 16907-K.)

LABEL FILED: January 26, 1949, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about November 12 and December 21, 1948, by Wm. H. Wexelberg & Co., from Chicago, Ill.

PRODUCT: 5 dozen devices known as *Magnetic Teething Necklace* at Milwaukee, Wis. Included with the devices was a circular entitled "This Is Not A Humbug." Examination showed that the device consisted of velvet covered strips of steel with ribbon at the ends for tying.

NATURE OF CHARGE: Misbranding, Section 502 (a), the pictures of a smiling baby wearing the necklace and a crying baby without the necklace, appearing in the labeling of the device, and the following statements in the labeling, together with similar statements in a foreign language, were false and misleading since the device was not effective in the treatment or prevention of the conditions stated and implied: (Carton) "The Magnetic Teething Necklace prevents children suffering during the teething period. Don't give your babies injurious medicines, but put one of our efficacious magnetic necklaces around baby's neck to be worn day and night, and you will be surprised at the results. It not only exerts a healthful influence on the growing teeth but imparts a beneficial effect on the whole system" (and circular) "This Is Not a Humbug. The Magnetic Teething Necklace the only genuine, original teething necklace Acts quickly, gently, stops pain safely. Prevent those sleepless nights * * * In weak and delicate children, on the other hand, the tooth penetrates the gums with difficulty, the infant becomes feverish and restless, and the most serious consequences may ensue. There is intense pain and swelling of the gums and the digestive organs become deranged. Various remedies have been recommended to relieve the pain during this trying period. Nothing has, however, proved so efficacious as the Magnetic Teething Necklace manufactured by us, which has obtained a wide reputation, and in the most distinguished circles. * * * When the child shows the first symptoms of teething, one of the necklaces is simply to be tied around its neck, and to be worn day and night. Not only will it exert an influence upon the growing teeth, but it will have a highly beneficial effect upon the system generally, and many of the sad consequences mentioned above will be averted by its simple means. * * * The Magnetic Teething Necklace 'I almost lost my baby girl when she was cutting teeth until I found your wonderful Necklace * * *' the Magnetic Teething Necklace has been a wonderful help so I am sending for another one' * * * 'They act like magic on a cross baby' * * * 'I used one for my boy and he had no trouble at all in getting his teeth. Now I want one for my baby girl' * * * For Baby's Sake * * * always have one of our Magnetic Teething Necklaces handy during the teething period. It is easier to prevent than to cure!"

DISPOSITION: February 21, 1949. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

2729. Adulteration and misbranding of Tim-Ball Solution. U. S. v. 8 Bottles * * *. (F. D. C. No. 26942. Sample No. 48174-K.)

LABEL FILED: March 22, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 30, 1948, by the Tim-Ball Liniment Co., from Arcadia, Calif.

PRODUCT: 8 1-pint bottles of *Tim-Ball Solution* at West Chester, Pa. Analysis showed that the product consisted of alcohol 48.1 percent, iodine, potassium iodide, eucalyptus oil, menthol, and salicylic acid.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since it was represented to contain 57.1 percent of alcohol, whereas the article contained materially less than that amount.

Misbranding, Section 502 (a), the following statements on the label of the article and in an accompanying circular were false and misleading since they represented and suggested that the article was effective in the treatment of disease conditions involving the legs of horses, whereas the article was not effective for such purposes: (Label) "Miracle Treatment for the Bad Leg Problem * * * Buck Shins, Big Knee * * * Swelling and Lameness * * * Osslets * * * Sprints, Ringbone," and (circular) "A Miracle Treatment For The Bad Leg Problem * * * Tim-Ball Solution * * * It Is Effective * * * It Goes To Work The Minute You Paint It On * * * Splints and Ringbone * * * Buck Shins * * * Sesimoid and Big Knee * * * Osslets."

DISPOSITION: April 26, 1949. Default decree and condemnation and destruction.

2730. Misbranding of Quinox. U. S. v. 151 Bottles * * *. (F. D. C. No. 26608. Sample No. 2308-K.)

LABEL FILED: February 18, 1949, District of Maryland.

ALLEGED SHIPMENT: On or about January 19, 20, 21, 26, and 27, 1949, by the Hopkins & Hopkins Pharmaceutical Co., from Philadelphia, Pa.

PRODUCT: 151 1-gallon bottles of *Quinox* at Snow Hill, Md. Analysis showed that the product consisted of 2.42 percent of sulfaquinoxaline in aqueous solution.

LABEL, IN PART: "Quinox (Solution of Sulfaquinoxaline) For Poultry."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article when used as directed was effective for the prevention of cecal coccidiosis and for the control of intestinal coccidiosis, whereas the article when used as directed would not be effective for such purposes.

DISPOSITION: March 17, 1949. Hopkins & Hopkins Pharmaceutical Co., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the product was ordered released under bond for reconditioning to increase the strength of the product and for relabeling to conform to the requirements of the Act.

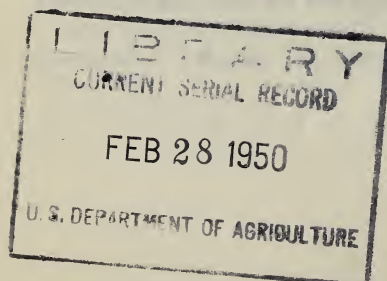
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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2731-2750

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., January 3, 1950.

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2731. Misbranding of Nanette Hormone Cream. U. S. v. Nix Cosmetics Co., Inc.
Plea of nolo contendere. Fine, \$800. (F. D. C. No. 23603. Sample Nos. 50260-H, 61334-H to 61336-H, incl.)

INFORMATION FILED: May 20, 1949, Western District of Tennessee, against the Nix Cosmetics Co., Inc., Memphis, Tenn.

ALLEGED SHIPMENT: Between the approximate dates of April 30, 1946, and March 21, 1947, from the State of Tennessee into the States of Alabama and Pennsylvania.

LABEL, IN PART: "Nanette Hormone Cream * * * Distributed By—Nanette Company Memphis 1, Tenn."

*For failure to bear a label containing an accurate statement of the quantity of the contents, No. 2732; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2733; cosmetic, subject to the drug provisions of the Act, No. 2731.

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Hormone Cream" and the label statement "Each 2 Oz. Contains 5 Mgs. Stilbestrol (Synthetic Estrogenic Substance)" were false and misleading since the name and the statement represented and suggested that the article contained a hormone and that it would exert a beneficial hormone-like, or beneficial estrogenic, effect upon the body when used as directed. The article did not contain a hormone and would produce no beneficial hormone-like, or beneficial estrogenic, effect upon the body when used as directed.

Further misbranding, Section 502 (f) (1), the directions for use in the labeling "Apply gently $\frac{1}{2}$ heaping teaspoonful at bedtime. Leave on overnight" were inadequate since they failed to indicate the conditions in which the article was to be used, the body area to which the article was to be applied, and the duration of its use.

DISPOSITION: May 20, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$800.

2732. Misbranding of Coxey-Lax. U. S. v. 24 Bottles * * *. (F. D. C. No. 26620. Sample No. 14188-K.)

LABEL FILED: March 2, 1949, Northern District of Indiana.

ALLEGED SHIPMENT: On or about December 3, 1948, by Jacob S. Coxey, Sr., from Massillon, Ohio.

PRODUCT: 24 bottles of *Coxey-Lax* at Tremont, Ind. Examination showed that the product consisted essentially of epsom salt, sugar, water, and extracts of plant drugs.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since the article was not effective in the treatment of the diseases and conditions stated and implied: "An Efficient Quick Tone-Up A Valuable Tone-Up * * * An efficient Tone-Up used in cleansing the liver, kidneys, bladder, blood streams, intestines and bowels; aiding in expelling gallstones, and poisonous matter from the body; and to correct constipation, nervousness, headaches, fatigues, and many of the common ailments; immediate relief from Acute indigestion, * * * After Bowels become regulated * * * A Priceless Possession Good Health; has been My Reward; From Using (Daily) Coxey-Lax For years I have traveled through the various parts of the country and many people have asked: How do you keep so young and spry? My reply has been, Coxey-Lax is responsible for it All; the continuous daily use of it (for twenty-five years), having aided digestion thru churning of food, cleansing and expelling poisonous matter from my intestines, liver, kidneys, bladder, body, and purifying my blood; has kept me feeling young, strong and active; never getting tired; only requiring five to eight hours sleep out of twenty-four * * * A tip: By taking Coxey-Lax once a day, it will keep a doctor away, and save \$2 trip and hospital bill."

Further misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (2), it was essentially a laxative and its labeling failed to warn that frequent or continued use of the article may result in dependence upon laxatives to move the bowels, and its labeling failed also to warn that the article should not be taken in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis.

DISPOSITION: May 11, 1949. Default decree of condemnation and destruction.

2733. Misbranding of Green Colored Transparent Plastic Strips, Red Colored Transparent Plastic Strips, Albert Christy's F & K Capsules, Albert Christy's Vitamin A and C Capsules, Albert Christy's True Extract of Garlic Capsules, Albert Christy's Calvite Calcium Phosphorus and Vitamin D Capsules, and Albert Christy's Tocopherol Capsules. U. S. v. 31 Green Colored Transparent Plastic Strips, etc. (F. D. C. No. 26592. Sample Nos. 26983-K, 26985-K, 27873-K to 27876-K, incl., 27879-K, 27880-K.)

LIBEL FILED: February 15, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: A portion of the products, together with a number of booklets, were shipped from Cincinnati, Ohio, by Albert Christy, on or about December 20, 1948, and a portion of the products were shipped from Detroit, Mich., by the Freshman Vitamin Co., on or about December 30, 1948.

PRODUCT: 31 *Green Colored Transparent Plastic Strips*, 16 *Red Colored Transparent Plastic Strips*, 299 60-capsule boxes of *Albert Christy's F & K Capsules*, 231 60-capsule boxes of *Albert Christy's Tocopherol Capsules*, 122 30-capsule boxes of *Albert Christy's Vitamin A and C Capsules*, 28 50-capsule packages of *Albert Christy's True Extract of Garlic Capsules*, and 239 60-capsule packages of *Albert Christy's Calvite Calcium Phosphorus and Vitamin D Capsules* at St. Louis, Mo., together with a number of booklets entitled "Practical Consideration concerning the Purpose and Classifications of Vitamins and Minerals Said to be Necessary Food and Body Elements."

LABEL, IN PART: "Albert Christy's F & K Capsules A Food Supplement Ingredients in Each Capsule: Free Fatty Acids of Linoleic and Linolenic Acids 3 minims, plus one-tenth Mg. Vitamin K. * * * Directions: As a dietary supplement, one capsule per day," "Albert Christy's Tocopherol Capsules A food supplement Each capsule contains a concentrate of natural mixed tocopherols distilled from vegetable oils equivalent to 30 Mg. of Alpha Tocopherol (Vitamin E) * * * As a dietary supplement, one capsule per day. One of these capsules contains as much Vitamin E approximately as is found in 90 plain wheat germ oil capsules, of the same size. Not for medicinal use," "Albert Christy's Vitamin 'A' and 'C' Capsules A Food Supplement Each Capsule Contains: Vitamin A 5,000 U. S. P. units (from carotene) Vitamin C 600 U. S. P. units (ascorbic acid). Each capsule will supply the full minimum adult daily requirements of Vitamin A and C. Directions: As a dietary supplement, one capsule per day," "Albert Christy's True Extract of Garlic in Edible Vegetable Oils * * * A Food Supplement Oderless true extract of garlic in the same proportion as found in the whole fresh garlic bulb suspended in pure vegetable oils. * * * As a dietary supplement, two capsules per day," and "Albert Christy's Calvite Calcium Phosphorus and Vitamin D Each Capsule Contains: Vitamin D (irradiated ergosterol) 333 U. S. P. Units Dicalcium Phosphate Anhydrous 261.9 Mg. Calcium Gluconate 162 Mg. * * * As a dietary supplement, two capsules will supply over the minimum adult daily requirement of Vitamin D; 6-20 of the daily requirement of calcium; and approximately 1-3 this requirement of phosphorus. Not for medicinal use."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labelings of all of the articles failed to bear adequate directions for use for the purposes for which

the articles were intended; and, Section 502 (b) (1), the *Green Colored Transparent Plastic Strips* and the *Red Colored Transparent Plastic Strips* failed to bear labels containing the name and address of the manufacturer, packer, or distributor.

Further misbranding, Section 502 (a), certain statements in the booklets were false and misleading. These statements represented and suggested that the *Albert Christy's F & K Capsules*, the *Albert Christy's Tocopherol Capsules*, the *Albert Christy's Vitamin A and C Capsules*, and the *Albert Christy's Calvite Calcium Phosphorus and Vitamin D Capsules* would be effective to give one the ability to resist infection, to assimilate and utilize food normally, and to attain a general feeling of health and well-being; that the *Albert Christy's F & K Capsules* would be further effective to supply the needs of nails, hair, eyes, and skin; that the *Albert Christy's Tocopherol Capsules* would be further effective to promote general fitness, prevent impairment of mental alertness, and to profoundly affect the entire glandular system; that the *Albert Christy's Vitamin A and C Capsules* would be further effective to protect the respiratory tract against infection, to maintain and build resistance to colds, to promote growth and increase the life span, to prevent retarded growth, poor resistance to infections, lack of vigor, poor appetite, dry skin, weakness, sterility, loss in weight, and such infections as are common in various types of pyogenic processes affecting the eyes, tear ducts, tongue, alimentary tract, ear canal, sinuses, bladder, and kidneys, and would be effective to build and maintain strong teeth and bones, to improve the appetite, and to stimulate growth and tissue respiration; and that the *Albert Christy's Calvite Calcium Phosphorus and Vitamin D Capsules* would be further effective to prevent restlessness, lack of vigor, enlarged joints, curved spine, and retarded growth. The articles would not be effective for such purposes.

DISPOSITION: March 24, 1949. Default decree of condemnation and destruction.

2734. Misbranding of *Sun-O-Ray Compound* and *Sun-O-Ray Inhalator*. U. S. v. 93 Bottles, etc. (F. D. C. No. 26603. Sample Nos. 46440-K, 46521-K.)

LABEL FILED: February 16, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about January 17 and 18, 1949, from Chicago, Ill.

PRODUCT: 93 1-ounce bottles and 22 4-ounce bottles of *Sun-O-Ray Compound* and 85 *Sun-O-Ray Inhalators* at St. Louis, Mo., in possession of George R. Thurman. The articles were offered by Mr. Thurman during lectures delivered by him in St. Louis on January 28, 29, and 31, 1949, for sinusitis, arthritis, asthma, weak eyes, running of the ears, loss of teeth, polio, and tuberculosis; for lubricating the eyes and joints; and for killing germs and purifying the air.

Analysis showed that the compound consisted of a mixture of volatile oils, including eucalyptus oil, camphor, and menthol, and that the inhalators consisted of glass tubes constricted at one end, and containing a wad of cotton between two perforated corks.

LABEL, IN PART: "Sun-O-Ray Compound [or "Inhalator"] Sun-O-Ray Products
* * * Chicago, Ill."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 18, 1949. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2735. Adulteration of distilled water. U. S. v. 676 Vials * * *. (F. D. C. No. 26145. Sample Nos. 11117-K, 11118-K.)

LIBEL FILED: December 22, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about February 19, 1948, from Los Angeles, Calif.

PRODUCT: 676 50-cc. vials of *distilled water* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: January 14, 1949. Default decree of condemnation and destruction.

2736. Adulteration of physiological salt solution. U. S. v. 2,988 Vials * * *. (F. D. C. No. 26136. Sample No. 11116-K.)

LIBEL FILED: December 16, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about February 19, 1948, from Los Angeles, Calif.

PRODUCT: 2,988 vials of *physiological salt solution* at New York, N. Y.

LABEL, IN PART: "Physiological Salt Solution (Isotonic Solution of Sodium Chloride U. S. P.) Sterile."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sterile Isotonic Sodium Chloride Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: January 14, 1949. Default decree of condemnation and destruction.

2737. Adulteration of thiamine hydrochloride solution and dextrose solution. U. S. v. 33 Vials, etc. (F. D. C. No. 26268. Sample Nos. 23585-K, 23593-K.)

LIBEL FILED: January 13, 1949, Northern District of Texas.

ALLEGED SHIPMENT: On or about October 19 and 30 and December 1, 1948, from Los Angeles, Calif.

PRODUCT: 33 15-cc. vials of *thiamine hydrochloride solution* and 35 50-cc. vials of *dextrose solution* at Dallas, Tex.

NATURE OF CHARGE: Adulteration, Section 501 (b), the articles purported to be and were represented as "Thiamine Hydrochloride Injection" and "Dextrose Injection," drugs the names of which are recognized in the United States Pharmacopoeia, and the quality and purity of the articles fell below the official standard since they were contaminated with undissolved material. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: May 25, 1949. Default decree of condemnation and destruction.

2738. Adulteration of sodium sulfadiazine solution. U. S. v. 125 Ampuls * * *.
(F. D. C. No. 26019. Sample No. 1319-K.)

LIBEL FILED: On or about November 16, 1948, Northern District of Georgia.

ALLEGED SHIPMENT: Between the approximate dates of April 2, 1947, and March 31, 1948, from Indianapolis, Ind.

PRODUCT: 125 20-cc. ampuls of *sodium sulfadiazine solution* at Atlanta, Ga.

LABEL, IN PART: "Ampul Solution Sodium Sulfadiazine 25% W/V * * *
Use only intravenously."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it was represented to possess since it was represented for intravenous use and was contaminated with undissolved material, whereas an article represented for intravenous use should be substantially free of any undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 10, 1948. Default decree of condemnation and destruction.

2739. Adulteration of Bromsulphalein. U. S. v. 20 Boxes * * *. (F. D. C. No. 26901. Sample No. 57795-K.)

LIBEL FILED: April 4, 1949, Southern District of California.

ALLEGED SHIPMENT: On or about December 28, 1948, by Hynson, Westcott & Dunning, Inc., from Baltimore, Md.

PRODUCT: 20 boxes of *Bromsulphalein* at Wilmington, Calif.

LABEL, IN PART: (Box) "Ten Ampules 3-cc. Size Bromsulphalein (H. W. & D. Brand of Sulfobromophthalein Sodium U. S. P. * * *) Sterile 5% Aqueous Solution Lot No. 335."

NATURE OF CHARGE: Adulteration, Section 501 (b), the product purported to be and was represented as a drug, "Sulfobromophthalein Sodium Injection," the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: May 16, 1949. Default decree of condemnation and destruction.

2740. Adulteration and misbranding of estrogenic substance. U. S. v. 91 Vials * * *. (F. D. C. No. 26555. Sample No. 15268-K.)

LIBEL FILED: March 7, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about November 11, 1948, by the Estro Chemical Co., from New York, N. Y.

PRODUCT: 91 10-cc. vials of *estrogenic substance* at Chicago, Ill.

LABEL, IN PART: "Aqua-Gyne Aqueous Estrogenic Substance."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 97 percent of the amount of estrone necessary to produce a potency of 20,000 International Units per cubic centimeter.

Misbranding, Section 502 (a), the label statement "Each cc * * * contains * * * (Estrogenic Substances predominantly Estrone) * * * (Ketosteroids as Estrone, approximately 97% by potency) * * * equivalent to 20,000 I. U. (assayed in terms of Estrone)" was false and misleading as applied to an article which contained materially less than 97 percent of

the amount of estrone necessary to produce a potency of 20,000 International Units per cubic centimeter.

DISPOSITION: May 24, 1949. Default decree of condemnation and destruction.

2741. Adulteration and misbranding of cotton swabs. U. S. v. 142 Cartons * * *.
(F. D. C. No. 26447. Sample No. 4716-K.)

LIBEL FILED: January 31, 1949, District of Massachusetts.

ALLEGED SHIPMENT: On or about November 10, 1948, by Steri-Swab, Inc., from Jamaica, Long Island, N. Y.

PRODUCT: 142 cartons of *cotton swabs* at Worcester, Mass.

LABEL, IN PART: "200 Uni-Swabs * * * The Only Sterile Swabs * * * Always remains sterile."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it was not sterile but was contaminated with living organisms.

Misbranding, Section 502 (a), the label statements "The Only Sterile Swabs" and "Always remains sterile" were false and misleading as applied to a product that was not sterile.

DISPOSITION: April 4, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2742. Misbranding of Nucone. U. S. v. Alva Irvin Cotterman (Nuco Products Co.).
Plea of guilty. Fine, \$100. (F. D. C. No. 25628. Sample Nos. 44432-K, 44433-K.)

INFORMATION FILED: March 11, 1949, Southern District of Ohio, against Alva Irvin Cotterman, trading as the Nuco Products Co., West Union, Ohio.

ALLEGED SHIPMENT: On or about August 10, 1948, from the State of Ohio into the State of Kentucky.

LABEL, IN PART: "Nucone * * * Contents: Oil of Sassafras, Smilax, Sweet Burch, Methyl-Salicylate."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, which included a form letter beginning with the words "A Letter from the original maker: Nucone is Registered," a form letter beginning with the words "A Letter from the original Maker: Nucone is a Medicine," and circulars entitled "Read What Users Have To Say About Nucone" and "Almost Unbelievable Letters," were false and misleading. The statements represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of neuritis, rheumatism, arthritis, neuralgia, sinus trouble, and all muscular conditions; that it would be efficacious in the treatment of conditions affecting all organs of the body; and that it was made under the provisions of the Pure Food and Drug Act and was registered under the provisions of that act. The article would not be efficacious for the purposes represented, and it was not made, nor was it registered, under the provisions of the Pure Food and Drug Act.

DISPOSITION: May 13, 1949. A plea of guilty having been entered, the court imposed a fine of \$100.

*See also Nos. 2731-2733, 2740, 2741.

2743. Misbranding of Gen-Con. U. S. v. 2 Cases * * *. (F. D. C. No. 26842. Sample No. 51255-K.)

LIBEL FILED: March 11, 1949, Western District of Kentucky.

ALLEGED SHIPMENT: On or about October 1, 1946, by the Gen-Con Co., from Canton, Ohio.

PRODUCT: 2 cases, each containing 72 bottles, of *Gen-Con* at Louisville, Ky. Analysis showed that the product consisted essentially of water, hydrochloric acid, and a coloring material.

LABEL, IN PART: "Gen-Con The 15 Drop Remedy."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Remedy for Indigestion * * * Relief for Gas, Heartburn, Headache, Stomach Disorders" were false and misleading since the article was not effective in the treatment of these conditions.

DISPOSITION: June 6, 1949. Default decree of condemnation and destruction.

2744. Misbranding of theophylline preparation. U. S. v. 9 Bottles * * *. (F. D. C. No. 26122. Sample No. 19458-K.)

LIBEL FILED: December 10, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about March 17, 1948, from Seymour, Ind.

PRODUCT: 9 1-pint bottles of *theophylline preparation* at Cincinnati, Ohio. Examination showed that the product consisted of a sirupy liquid and a precipitate. The supernatant sirup liquid contained, per 4 cc., .093 gram (1.44 grains) of theophylline. The precipitate consisted of theophylline.

LABEL, IN PART: "Brand of Theophylline Sodium Glycinate * * * Each Teaspoonful (4 cc.) contains * * * (equivalent to 0.16 Gm. (2½ gr.) Theophylline U. S. P.)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the above-quoted statements on the label were misleading since the sirup contained per 4 cc. less than the equivalent of 0.16 gram (2½ grains) of theophylline, namely, .093 gram (1.44 grains). The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: January 6, 1949. Default decree of condemnation and destruction.

2745. Misbranding of Burnett's Radio Active Emanator. U. S. v. William Henry Burnett. Plea of *nolo contendere*. Fine, \$100. (F. D. C. No. 24250. Sample No. 49567-H.)

INFORMATION FILED: March 25, 1948, Eastern District of Arkansas, against William Henry Burnett, Kingsland, Ark.

ALLEGED SHIPMENT: On or about February 28, 1947, from the State of Arkansas into the State of Mississippi.

PRODUCT: Examination showed that the device was a concrete molded block exhibiting a negligible degree of radioactivity.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying pamphlets entitled "Nature's Health Restorer" and "Burnett's Radio Active Emanator A Health Spring In Your Home" were false and misleading since the device would not fulfill the promises of benefit suggested and implied. These statements represented and suggested that the device would be a health spring in the home, would impart beneficial qualities to water, and would soften and purify the hardest waters; that it would be efficacious in

the treatment of kidney disorders, diabetes, high blood pressure, stomach troubles, rheumatism, arthritis, neuritis, asthma, and various kindred troubles; that it would promote digestion, give increased vigor to all nutritive processes, stimulate the intellectual qualities, prevent insanity, rouse noble emotions by promoting a healthy brain, retard the advance of old age, and create splendid, youthful, and joyous life; that it would carry stimulating energy-giving action to every cell in the blood stream, restore the body functions and enable the user to remain well; that it would restore vigor to men and women of advanced years, increase the red blood count, kill or check disease germs, and relieve pain; that it would relieve the pain of acute and chronic gout, neuralgia, sciatica, and lumbago, and relieve the lancinating pains of tabes dorsalis; that it would be efficacious in the treatment of high blood pressure and arteriosclerosis; that it would promote normal functioning of the ductless glands; that it would have a stimulating effect upon the sexual organs and would restore youth to the user; and that it would restore health, readjust the system to a more normal condition, and build and renew the system.

DISPOSITION: April 28, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$100.

2746. Misbranding of Glo Oscillating Massager. U. S. v. 64 devices * * *.
(F. D. C. No. 26138. Sample No. 4719-K.)

LABEL FILED: December 17, 1948, District of Massachusetts.

ALLEGED SHIPMENT: On or about November 4, 1948, by Glo Industries, Inc., from New York, N. Y.

PRODUCT: 64 *Glo Oscillating Massagers* at Boston, Mass., together with a number of leaflets entitled "Glo For Health," 3 large placards entitled "Glo For Health," 4 metal placards headed "Free Demonstration," and a wooden sign bearing the words "Stop Pain use Glo." The device consisted of a dome-shaped plastic case with a handle attached, through which an electric connecting cord entered the dome. A vibrator and a heating unit were inside the dome.

LABEL, IN PART: (Carton) "Glo Oscillating Massager with Infra-Red Heat."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the leaflets, placards, and wooden sign were false and misleading since they represented and suggested that the device was an effective treatment for sprains, many common discomforts, sprained nerves, aches and pains, cold miseries, aches and pains of colds, chest congestion, sinusitis, congestion, rheumatism, arthritis, neuritis, and cramps; that it was an effective treatment to stop pain; that heat of the device would penetrate deep down into the tissues of the body to relieve pains and misery; and that its use would insure healthy facial muscles and tissue. The device would not fulfill the promises of benefit stated and implied.

DISPOSITION: April 21, 1949. Glo Industries, Inc., New York, N. Y., claimant having consented to the entry of a decree, judgment of condemnation was entered and the devices were ordered released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

2747. Misbranding of *Iocrepogal Tablets*, *Special Formula Tablets*, and *Dr. Gatchell's Tonic Tablets*. U. S. v. 11 Dozen Bottles, etc. (F. D. C. No. 25110. Sample Nos. 21322-K, 21323-K, 21374-K.)

LABEL FILED: On or about August 2, 1948, Western District of Missouri.

ALLEGED SHIPMENT: On or about September 14, 1946, and October 28, 1947, from *Curtis-Folse Laboratories*, Kansas City, Kans.

PRODUCT: 11 dozen bottles of *Iocrepogal Tablets*, 30,000 *Special Formula Tablets* in a bulk container, and 11 dozen bottles of *Dr. Gatchell's Tonic Tablets* at Kansas City, Mo., in possession of Dr. J. W. Gatchell. The *Iocrepogal Tablets* had been repackaged and labeled by the consignee from a bulk shipment labeled in part "Creodine Tablets," and the *Dr. Gatchell's Tonic Tablets* had been repackaged from the bulk shipment of *Special Formula Tablets*.

Examination showed that the *Iocrepogal Tablets* contained calcium iodide, calcium carbonate, and creosote, and that the *Special Formula Tablets* and *Dr. Gatchell's Tonic Tablets* contained in each tablet not less than .002 grain of strychnine and not more than 1/30 grain, if any, of powdered extract of *nux vomica*.

NATURE OF CHARGE: The *Iocrepogal Tablets* and the *Dr. Gatchell's Tonic Tablets* were misbranded while held for sale after shipment in interstate commerce, and the bulk shipment labeled *Special Formula Tablets* was misbranded while in interstate commerce, in the following respects:

Iocrepogal Tablets. Section 502 (a), the statement on the bottle label "For the treatment of dogs suffering from Respiratory Infections, Coughs, Colds, Bronchitis, Laryngitis and Catarrhal conditions of the bowels" was false and misleading since the article was not effective in the treatment of dogs suffering from such conditions; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

Special Formula Tablets. Section 502 (a), the label statement on the bulk container of the tablets "Po Ext Nux Vomica 1/10 gr (Strychnine .001 gr)" was false and misleading as applied to a product containing not more than 1/30 grain, if any, of powdered extract of *nux vomica* and not less than 0.002 grain of strychnine.

Dr. Gatchell's Tonic Tablets. Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to state the quantity and proportion of strychnine and arsenic sulfide present in the article.

DISPOSITION: February 10, 1949. Default decree of destruction.

2748. Misbranding of *Campbell's Chemical Mix*. U. S. v. 9 Cartons * * *. (F. D. C. No. 26961. Sample No. 49147-K.)

LABEL FILED: April 18, 1949, District of Wyoming.

ALLEGED SHIPMENT: On or about November 18, 1948, by the S & L Campbell Co., from Dupont, Colo.

PRODUCT: 9 3-pound cartons of *Campbell's Chemical Mix* at Wheatland, Wyo. Examination showed that the product consisted essentially of ammonium chloride, with relatively small proportions of sodium chlorate and potassium chlorate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading: "Campbell's Chemical Mix for Cattle and

Sheep * * * put one 3-lb. package of Campbell's Chemical Mix to 100 lbs. No. 4 salt and mix thoroughly. Put in troughs where they can have access to it at all times. When feeding dairy cows chop or bran, put $\frac{1}{4}$ teaspoonful in the chop or bran twice daily out of the 3-lb. package. For drench, mix one teaspoonful in $\frac{3}{4}$ quart of water and drench. We recommend force feeding when grain is fed—feed about 2 or 3 days before turning on clover or alfalfa." The above statements represented and suggested that the article was a remedy for the diseases of cattle and sheep, for any ill effects upon sheep and cattle resulting from eating alfalfa or clover, or upon dairy cows from eating chop or bran; and for preventing ill effects upon cattle from grazing on clover or alfalfa. The article when administered in accordance with the instructions on the label would not be effective for the treatment or prevention of any disease of sheep or cattle.

DISPOSITION: June 24, 1949. The shipper of the product having accepted service of the libel and authorized the entry of a final decree, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF OMISSION OF, OR UNSATISFACTORY, INGREDIENTS STATEMENTS*

2749. Misbranding of solution of estrogenic hormone. U. S. v. 64 Bottles * * *. (F. D. C. No. 25971. Sample No. 31626-K.)

LIBEL FILED: November 4, 1948, Southern District of California.

ALLEGED SHIPMENT: On or about August 12, 1948, from Brooklyn, N. Y.

PRODUCT: 64 30-cc. bottles of solution of *estrogenic hormone* in the possession of Medi-Synth Laboratories, Inc., Los Angeles, Calif., which bottled this product from a bulk shipment consisting of 2 bottles, 2½-liter size, labeled in part "a Estradiol in Microsuspension."

LABEL, IN PART: (After repacking) "Solution Estrogenic Hormone (Aqueous Microsuspension) 20,000 International Units per cc. rated in Estrone units."

NATURE OF CHARGE: Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of the active ingredient, "alpha-estradiol." The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 19, 1948. Medi-Synth Laboratories, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling under the supervision of the Federal Security Agency.

2750. Misbranding of Ung. Hydrophen. U. S. v. 75 Tubes * * *. (F. D. C. No. 25711. Sample No. 41689-K.)

LIBEL FILED: November 2, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about September 9, 1948, by Goodwin Laboratories, Inc., from New York, N. Y.

*See also No. 2747.

PRODUCT: 75 1-ounce tubes of *Ung. Hydrophen* at Chicago, Ill. Examination showed that each gram of the product contained approximately 0.6 milligram of phenylmercuric nitrate and 10 milligrams of benzocaine, an analgesic drug.

LABEL, IN PART: "Ung. Hydrophen * * * An ointment of high potency; low toxicity."

NATURE OF CHARGE: Misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear a statement of the quantity or proportion of phenylmercuric nitrate, a derivative of mercury, and the name of benzocaine, an active ingredient, contained therein.

DISPOSITION: March 9, 1949. Default decree of condemnation and destruction.

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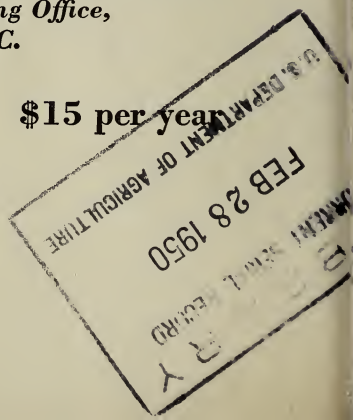
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**FEDERAL SECURITY AGENCY
FOOD AND DRUG ADMINISTRATION**

**NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2751-2770

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., January 3, 1950.

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DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS*

2751. Misbranding of Orange Blossom Suppositories. U. S. v. 79 Packages * * *
(and 2 other seizure actions). (F. D. C. Nos. 26219, 26359, 26375.
Sample Nos. 27495-K, 45875-K, 45879-K.)

LIBELS FILED: December 14, 1948, and January 3, 1949, Eastern District of Missouri and Western District of Tennessee.

ALLEGED SHIPMENT: On or about November 8 and 17 and December 6, 1948, by the Dr. J. A. McGill Co., Not Inc., from Chicago, Ill.

PRODUCT: *Orange Blossom Suppositories.* 79 packages at St. Louis, Mo., and 242 packages at Memphis, Tenn. Each package contained 6 suppositories. Examination showed that the product was semisolid suppositories consisting essentially of ammonium alum, borax, petrolatum, talc, and powdered cocoa.

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil and at bed time insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days. The use of Orange Blossom Suppositories is not recommended at the menstrual period or during pregnancy."

DISPOSITION: January 6 and February 3, 1949. Default decrees of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2752. Misbranding of herb preparations. U. S. v. Arthur Cox. Plea of guilty.
Fine, \$100. (F. D. C. No. 23212. Sample Nos 14065-H, 22745-H, 27167-H.)

INFORMATION FILED: August 1, 1947, Southern District of Indiana, against Arthur Cox, Sullivan, Ind.

ALLEGED SHIPMENT: Between the approximate dates of February 27 and April 30, 1946, from the State of Indiana into the States of Illinois and Colorado.

PRODUCT: Analyses disclosed that there were four different types of *herb preparations*, namely, a light brown colored liquid with an odor of peppermint, containing chiefly water and plant extractives and a small amount of emodin bearing drugs; a black ointment containing chiefly oil of mustard in a grease-type base; plant material consisting chiefly of stems and leaf fragments, with an odor and appearance resembling that of hay; and a black syrupy liquid consisting essentially of water, reducing sugar, and plant extractives, including emodin bearing drugs.

LABEL, IN PART: "Arthur Cox Log Saw Herb Preparations."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the articles failed to bear labels containing the place of business of the manufacturer, packer, and

*See also No. 2766.

distributor; and, Section 502 (b) (2), the containers of the articles bore no labels containing a statement of the quantity of the contents.

Further misbranding, Section 502 (a), the statement "Recommended for sinus" on the label of the light brown colored liquid was false and misleading since the article would not be efficacious in the cure, mitigation, and treatment of sinus diseases; Section 502 (e) (2), the ointment was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the ointment bore no directions for use, and the labeling of the plant material and syrupy liquid failed to bear adequate directions for use since the labeling failed to reveal the conditions for which the articles were to be used.

DISPOSITION: January 24, 1949. A plea of guilty having been entered, the court imposed a fine of \$100.

2753. Misbranding of serenium tablets. U. S. v. 7 Bottles * * *. (F. D. C. No. 25870. Sample No. 8347-K.)

LIBEL FILED: October 21, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about May 24, 1948, by E. R. Squibb & Sons, from Brooklyn, N. Y.

PRODUCT: 7 bottles of *serenium tablets* at Newark, N. J.

LABEL, IN PART: "50 Tablets List 7974 Chocolate Coated Serenium."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling failed to bear adequate directions for use since the directions for use which appeared on the bottle label "For oral treatment of certain urinary infections. Dose: Adults, 1 tablet by mouth 3 times daily before meals; children over 3 years, $\frac{1}{2}$ tablet twice daily; children under 3 years, $\frac{1}{4}$ tablet twice daily" were not adequate directions for use in the treatment of urinary infections.

DISPOSITION: May 23, 1949. Default decree of condemnation and destruction.

2754. Misbranding of succinol tablets. U. S. v. 15 Bottles * * *. (F. D. C. No. 27235. Sample No. 12373-K.)

LIBEL FILED: May 20, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about April 27, 1949, by the Succinol Co., from New York, N. Y.

PRODUCT: 15 100-tablet bottles of *succinol tablets* at Philadelphia, Pa.

LABEL, IN PART: "Succinol Each tablet contains 0.2 Gm. Phenylsemicarbazide * * * To be used only by or on the prescription of a physician * * * The Succinol Company, New York 7, N. Y."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users since the article contained phenylsemicarbazide and its labeling failed to warn that phenylsemicarbazide is capable of producing serious hemolytic anemia.

DISPOSITION: June 21, 1949. The Succinol Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling.

2755. Misbranding of Brandenfels' Scalp and Hair Treatment. U. S. v. 43 Bottles, etc. (F. D. C. No. 21914. Sample Nos. 39009-H, 39010-H.)

LIBEL FILED: December 4, 1946, Eastern District of Michigan; amended libel filed May 3, 1948, Western District of Washington.

ALLEGED SHIPMENT: On or about November 7, 1946, by Carl Brandenfels, from St. Helens, Oreg.

PRODUCT: 43 16-ounce bottles and 43 8-ounce bottles of *Brandenfels' Scalp and Hair Treatment* at Detroit, Mich. Examination of the 16-ounce bottles of the product showed that the product consisted essentially of about $\frac{1}{4}$ gram of sulfanilamide in each 100 cc., water, and cornstarch, and that the product in the 8-ounce bottles consisted essentially of a perfumed emulsion of oil in water.

LABEL, IN PART: "Brandenfels' Scalp and Hair Treatment Formula A * * * Contents: 16 Ounces [or "Formula B * * * Contents: 8 Ounces"]."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Scalp and Hair Treatment" and "The Hair Farmer" were false and misleading since they represented and suggested that the articles when used as directed were effective in promoting the growth of hair, whereas the articles were not effective for such purposes.

Further misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use by reason of its failure to state all of the conditions for which the articles were intended, namely, growing hair in bald areas, curing dandruff, and stopping falling hair from continuing to fall out, as well as promoting the growth of hair; and, further, the labeling of the articles failed to bear adequate directions for use in the conditions, namely, growing hair in bald areas, curing dandruff, stopping falling hair from continuing to fall out, and promoting the growth of hair, for which they were prescribed, recommended, and suggested in their labeling and in their advertising disseminated and sponsored by and on behalf of their manufacturer and packer.

DISPOSITION: Carl Brandenfels, Inc., appeared as claimant and filed an answer denying the allegations of the libel. Thereafter, pursuant to stipulation by the parties, the case was removed for trial to the Western District of Washington on December 22, 1947. On March 16, 1949, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered destroyed.

DRUG ACTIONABLE BECAUSE OF THE PRESENCE OF A NONCERTIFIED COAL-TAR COLOR*

2756. Adulteration of Meth-O-Sol and alleged misbranding of Benz-Cal-Cin. U. S. v. Crescent-Kelvan Co., Jeremiah T. Roach, and George Duke Lambert. Pleas of not guilty. Tried to the jury. Verdict of guilty. Fine of \$1.00 against company; each individual fined \$500 and placed on probation for 2 years. Judgment of conviction reversed upon appeal and case retried upon pleas of not guilty. Count 2 dismissed and verdict of guilty returned on count 1. Fine of \$1 against company, \$100 against defendant Roach, and \$150 against defendant Lambert.

*See also No. 2766.

Imposition of prison sentence suspended and each individual placed on probation for 1 year. (F. D. C. No. 15500. Sample Nos. 79916-F, 79919-F.)

INFORMATION FILED: March 7, 1946, Eastern District of Pennsylvania, against the Crescent-Kelvan Co., an association, Philadelphia, Pa., Jeremiah T. Roach, president, and George Duke Lambert, secretary-treasurer of the company.

ALLEGED SHIPMENT: On or about March 7 and June 22, 1944, from the State of Pennsylvania into the State of Maryland.

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), and misbranding, Section 502 (e). The charges of adulteration against the *Meth-O-Sol* and misbranding against the *Benz-Cal-Cin* are given in the court opinion set forth below.

DISPOSITION: Pleas of not guilty having been entered, the case came on for trial before a jury, and at the conclusion of the trial on January 17, 1947, the jury returned a verdict of guilty. A motion for a new trial was made on behalf of the defendants, and on January 31, 1947, the motion was denied. On the same date, the court imposed a fine of \$1 against the company and a fine of \$500 against each individual and placed the individuals on probation for a period of 2 years. Notice of Appeal to the United States Court of Appeals for the Third Circuit was thereupon filed on behalf of the defendants, and on January 26, 1948, after consideration of the briefs and arguments of counsel, the following opinion was handed down by that court:

Biggs, *Circuit Judge*: "The information in the case at bar charges Crescent-Kelvan Company and the individual defendants in two separate counts with violations of the Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 675, Section 1 et seq., 52 Stat. 1040 (1938), 21 U. S. C. § 301 et seq. (Supp. 1946).

"The first count charges that the defendants caused to be shipped in interstate commerce a drug, known by the trade name of 'Methosol,' adulterated within the purview of Section 501 (a) (4) of the Act, 21 U. S. C. A. § 351 (a) (4) (Supp. 1946), in that it contained, for purpose of coloring only, a coal-tar color, 'Butter Yellow,' actually dimethylamino-azobenzene, which had not been certified for use in accordance with the regulations¹ promulgated under Section 504 of the Act, 21 U. S. C. A. § 354 (Supp. 1946). The defendants do not contend that the drug was not within the purview and prohibition of the statute. Their defenses lie on other grounds which will be dealt with hereinafter.

"The second count charges a violation of Section 502 (e) of the Act, 21 U. S. C. A. § 352 (e) (Supp. 1946), in that the defendants caused to be shipped in interstate commerce certain capsules in a bottle labeled in pertinent part as follows: '1000 (Capsules) BENZ-CAL-CIN, Trade Mark, Chemical Combination Benzoinated-Phenyl Cinchoninic Acid and Calcium. . . . Each capsule represents Phenyl cinchoninic acid approximately two grains.' The gravamen of the charge in the count is misbranding in that the drug, 'Benz-Cal-Cin,' a fabrication of two or more ingredients, was not designated solely by a name recognized in an official compendium, the label on the bottle failing to bear the common or used name of each active ingredient, viz., free cinchophen and cinchophen in chemical combination. The defendants contend that

¹ See 21 C. F. R. Cum. Supp., 135.1-15 (1944).

the name on the label 'phenylcinchoninic acid,' was a common or usual name of the drug.

"The facts as shown by the evidence are as follows: While the precise status of Crescent-Kelvan Company cannot be ascertained from the record, it is described in the information as 'an association existing as a business trust under the laws of the Commonwealth of Pennsylvania. . . .' The learned trial judge in his charge told the jury that it was an 'association,' and that an association 'simply means that they operate as a business trust, which they can properly do under the laws of the Commonwealth of Pennsylvania.' Exhibit G-7, a bill of the Crescent-Kelvan Company, states that it is 'A Trust,' and that the defendant Roach is its president and that the defendant Lambert is its secretary-treasurer, while M. W. Lambert is shown as 'Trustee.' It was stipulated by counsel that if the Prothonotary of the Court of Common Pleas, Philadelphia County, were to testify he would produce a certificate, June Term, 1941, C. P. No. 3, 475, signed by Roland J. Christy, dated August 27, 1941, registering under the fictitious name, Crescent-Kelvan Company, which was characterized as 'Chemists to the Medical Professions . . .' and filed by the defendant Lambert as treasurer. We think it may be assumed in the light of the foregoing that Crescent-Kelvan Company was registered under the Pennsylvania Fictitious Names Act, 54 PS Pa. § 21 (1930), and that it is a 'Massachusetts trust' of the sort referred to by the Supreme Court of Pennsylvania in *Pennsylvania Company, etc., v. Wallace*, 346 Pa. 532, 31 A. 2d 71. In any event it is clear that the defendant Roach purported to act as the president of Crescent-Kelvan Company and that the defendant Lambert purported to act as its secretary-treasurer; that the individual defendants were in charge of the books, records and premises of Crescent-Kelvan Company and that their acts on behalf of it are sufficient to bind the 'Trust.'

"In March, 1944, an inspector of the Philadelphia station of the Food and Drug Administration came to the plant of Crescent-Kelvan Company where the individual defendants were in charge, and inspected the premises. Wagner, the inspector, testified that the inspection was made to ascertain the use by Crescent-Kelvan Company of coal-tar colors in drug products and that he found in the plant a package labeled 'D & O,² 4 oz. color, No. 305, for technical use only.'; that he was informed that this coal-tar color was used in the defendant's product 'Methosol'; that he took a sample therefrom, without objection from the individual defendants, offering to pay for it, an offer which was refused.

"Wagner further testified that thereafter he inspected the shipping records of Crescent-Kelvan Company and found that Methosol had been shipped by it to a physician in Maryland, and that Benz-Cal-Cin capsules had been shipped to another doctor in the same State. The two doctors testified that they had received respectively from Crescent-Kelvan Company by parcel post Methosol and Benz-Cal-Cin capsules. There was further testimony by an agent of the Administration that samples of these drugs had been procured from the physicians. Chemists employed by the Administration testified that the Methosol thus procured contained the prohibited coal-tar coloring Butter Yellow and that the Benz-Cal-Cin capsules contained free cinchophen and cinchophen in chemical combination.

"The jury found all defendants guilty on the counts of the information and the court entered judgment of sentence imposing a fine on Crescent-Kelvan Com

² The product was distributed by Dodge & Olcott of New York City.

pany and sentencing the individual defendants to both fine and imprisonment, the sentences of imprisonment, however, being suspended and the individual defendants being placed upon probation. All the defendants have appealed.

"Substantially all of the testimony offered by the United States³ was subject to repeated objections by the defendants. This brings us immediately to a discussion of the first point raised by them as grounds for reversal. The inspector of the Food and Drug Administration entered the premises of Crescent-Kelvan Company without a search warrant. The defendants assert that they were deprived of the rights guaranteed to them by the Fourth Amendment of the Federal Constitution and that their effects were subjected to unreasonable search and seizure because the inspector made the inspection without a search warrant, because he obtained a sample of the prohibited coal-tar color and, above all, because he inspected the shipping records from which the names of the Maryland doctors were obtained. This inspection of course led ultimately to samples of Methosol and Benz-Cal-Cin capsules being introduced into evidence at the trial.

"Passing by the question as to whether or not the guarantees of the Fourth Amendment may be invoked by a 'Trust' such as that at bar, a question which we need not answer, we find it unnecessary to deal with the defendants' contentions at length for the following reasons. Section 704 of the Act, 21 U. S. C. A. § 374 (Supp. 1946), provides that officers designated by the Administrator, after first making a request and obtaining permission of the owner, or custodian are authorized to enter, at reasonable times, any factory in which drugs are manufactured, processed, packed or held, for introduction to interstate commerce; and to inspect, at reasonable times, such factory and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

"It is not contended that the inspector came upon the premises at an unreasonable time or forced his way into Crescent-Kelvan Company's plant. It is clear from the testimony that whether the inspector expressly requested leave to enter and received such permission from the individual defendants who were in fact in charge of the premises, leave and permission to enter were tacitly granted to the inspector by the individual defendants. Under the statute the inspector had the right to examine the package containing the prohibited coal-tar color, Butter Yellow. But even if the inspector had no express right under the statute to take a sample of the coal-tar color, the individual defendants consented and acquiesced in that taking. It is manifest also that whether or not the statute conferred upon the inspector the right to examine the shipping records of Crescent-Kelvan Company, permission to make such an inspection was implicitly granted to them by the individual defendants then present⁴ who had the right to bind the 'Trust.' We find

³ None was offered on behalf of the defendants.

⁴ Comparing the provisions of Section 704 of the Act 21 U. S. C. A., § 374 (Supp. 1946), with those of Section 703, 21 U. S. C. A., § 373 (Supp. 1946), relating to the inspection of drugs in the possession of carriers engaged in interstate commerce, it should be noted that the right to inspect shipping records is expressly conferred upon officers of the Administration. Since the right to inspect shipping records is not expressly conferred upon inspectors making inspections of factories, it may be argued that an inspection of a factory under the latter section would not include an inspection of the factory's shipping records. On the other side, it may be argued that inspection of a "factory" includes the inspection of everything to be found therein relating to the business of the factory. The latter view seems to us to be more in accord with the canons of statutory construction but it is unnecessary to decide this question in the case at bar.

it unnecessary, therefore, to embark upon a discussion of the authority granted to the inspector by the statute.

"We entertain no doubt that Section 704 is constitutional. Its provisions are bottomed upon the police power of the United States as exercised under the Commerce Clause of the Constitution for the protection of the public health.⁵ See *McDermott v. Wisconsin*, 228 U. S. 115, 128; *Hipolite Egg Co. v. United States*, 220 U. S. 45, 47, and *Seven Cases v. United States*, 239 U. S. 510. No constitutional right is violated by a statute, an ordinance or a regulation providing for the inspection of places of business, dealing with drugs or foods during business hours. See *Keiper v. City of Louisville*, 152 Ky. 691, 154 S. W. 18, *State ex rel. Melton v. Nolan*, 161 Tenn. 293, 30 S. W. 2d 601, and the authorities collected in 47 Am. Jur. pp. 508-510. By its express terms Section 704 provides for inspection of factory premises only after first obtaining permission from the custodian thereof. The section is patterned on Section 3601 of the Internal Revenue Code and the authority exercised under that statute has never been regarded as violative of the guarantees of the Fourth Amendment. See *Cooper v. United States*, 3 Cir., 299 F. 483; *United States v. Vlahos*, 19 F. Supp. 166 (Ore.); *In re Meador*, 16 F. Cas. No. 9375. See also *United States v. Barnes*, 222 U. S. 513, and *McDermott v. Wisconsin*, 228 U. S. 115. The inspector in examining the premises and the shipping records of Crescent-Kelvan Company did no act which constituted a violation of the Fourth Amendment.

"Other grounds asserted by the defendants, however, require reversal of the judgments of conviction and a new trial. These grounds go to the sufficiency of the charge. This subject requires a brief discussion of the offense laid in the second count of the information and of the terms of the statute alleged to have been violated.⁶ As we already stated the second count of the information is based on an alleged violation of Section 502 (e) of the Act which provides that a drug shall be deemed to be misbranded 'If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears . . . in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient . . . ' The drug contained in the Benz-Cal-Cin capsules was not designated 'solely' by a name recognized in an official compendium since it was described by the name 'Benz-Cal-Cin,' a trade name, and also was designated as a chemical combination, 'Benzoinated-Phenyl Cinchoninic Acid and Calcium.' The evidence presented shows that Benz-Cal-Cin was fabricated from two or more ingredients. Therefore, under the terms of the statute the active ingredient or ingredients should have been designated by their respective 'common or usual' name. The evidence offered will support the view that the active ingredient in the capsules was cinchophen or, as it is sometimes called, phenylcinchoninic acid.⁷ The question, therefore, was whether or not the label on the bottle containing the capsules designated the active ingredient by its common or usual name.

⁵ See Sen. Rep. No. 361, 74th Cong., 1st Sess., p. 26, and H. R. Rep. No. 2139, 75th Cong., 3rd Sess., pp. 2, 12.

⁶ No comment respecting the sufficiency of the first count of the information or the charge of the court below thereon is necessary for reasons already apparent.

⁷ Cinchophen or phenylcinchoninic acid apparently was the only active ingredient. Cinchophen or phenylcinchoninic acid are the same drug, sometimes also called phenylquinoline-carboxylic acid. See *The National Formulary*, 7th Edition, 1942, published by the American Pharmaceutical Association, at p. 95.

"What did Congress mean when it made use of the phrase 'common or usual name'? The adjective 'common' has a multiplicity of definitions, but the first and the usual definition is 'belonging or pertaining to the community at large . . . habitual or notorious . . .'.⁸ The adjective 'usual' is ordinarily deemed to be synonymous with the adjective 'common.' We think, therefore, that Congress intended that drugs should be labeled with the name by which they are known to the community at large. Cinchophen is a powerful drug which has been used as a diuretic in gout and to relieve acute articular rheumatism.⁹ Though we may assume that it cannot be procured without a prescription and that therefore it would come into the hands of a member of the public only when prescribed by a physician, none the less we are of the opinion that Congress did not intend to limit the designation of 'common or usual name' by some such further phrase as 'known to physicians or to druggists.' To hold to the contrary would be to amend the statute by judicial interpretation.

"Evidence was offered that the common or usual name of the active ingredient in the Benz-Cal-Cin capsules introduced by the defendants in interstate commerce was 'cinchophen.' The defendants, relying upon the provisions of Section 301 (a) of the Act, 21 U. S. C. A. § 331 (a) (Supp. 1946),¹⁰ and specifically on those of Section 201 (g) and (j) of the Act, 21 U. S. C. A. § 321 (g) and (j) (Supp. 1946),¹¹ seem to take the position that if the drug contained in the Benz-Cal-Cin capsules was designated on the bottle's label by a name employed in the official The National Formulary,¹² they were relieved from the criminal sanctions of the Act. In this they are in error. While The National Formulary refers to the drug under consideration as 'Cinchophen,' 'Phenylcinchoninic Acid' and 'Phenyl-Quinoline-Carboxylic Acid,'¹³ the employment of these names by The National Formulary must be treated only as evidence to be weighed by the jury, in addition to all the other evidence presented, as to what is the common or usual name of the drug. In other words, the question for the jury on this phase of the case is whether the descriptive term phenyl *cinchoninic acid* is the common or usual name of the drug, or whether the word *cinchophen* is its common or usual name as contended by the United States.

"The charge of the court below was insufficient in that it did not set out clearly and adequately this issue of fact. This was the vital issue presented by count 2 of the information and the evidence adduced thereunder. The failure of the trial court to charge the jury adequately on this point was error which requires reversal of the judgments of conviction on the second count.

⁸ See Webster's New International Dictionary, 2d Edition.

⁹ See The American Illustrated Medical Dictionary, Dorland, 19th Edition. The drug has since been removed from some formularies by reason of its propensity to cause acute jaundice.

¹⁰ Which provides: "The following acts and the causing thereof are hereby prohibited: (a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded." 52 Stat. 1042 (1938), 21 U. S. C. A. § 331 (Supp. 1946).

¹¹ As follows: "(g) The term 'drug' means (1) articles recognized in the . . . official National Formulary . . .; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals . . ." [and] "(j) The term 'official compendium' means the . . . official National Formulary . . .".

¹² The official "The National Formulary", 7th Edition, 1942, published by The American Pharmaceutical Association, p. 95, was introduced into evidence.

¹³ The word "Cinchophen," when first employed in the nomenclature of The National Formulary, is in boldface type. The other names in the nomenclature are not. Throughout the article respecting the drug in The National Formulary the reference is usually to "Cinchophen."

"Referring now to the charge generally, we find further error. The learned trial judge stated: 'Jeremiah T. Roach and George Duke Lambert [the individual defendants] are responsible as individuals under the law, and under this information, as it is drawn, for the acts committed by the company contrary to the Federal law.' As we have said the status of the defendant, Crescent-Kelvan Company, is not entirely clear, but putting to one side any question as to the precise nature of the association or trust it is clear that the court below charged that the individual defendants were responsible for the acts committed by Crescent-Kelvan Company. But even if there is evidence to support a conclusion by the jury that the individual defendants were responsible 'for the acts committed by the company' the charge is erroneous none the less. The learned District Judge in fact charged the jury that the individual defendants *were* responsible for the acts committed by Crescent-Kelvan Company. In effect he gave binding instructions in this respect. The trial court should have charged the jury in the usual way that if they believed the evidence of the responsibility of the individual defendants for the acts of Crescent-Kelvan Company to be worthy of credence, then they could find that the individual defendants were responsible for Crescent-Kelvan Company's misconduct. This portion of the charge was erroneous and worked prejudice to the individual defendants and to Crescent-Kelvan Company as well.

"The trial court also, quite inadvertently we know, fairly consistently throughout its charge stated that the guilt of the defendants was to be proved, to quote a typical instance, 'by proving by preponderance of the evidence their wrongdoing'. This misstatement was called to the court's attention by counsel for the defendants at the close of the charge and the court then charged that the United States 'has the burden throughout the trial of establishing, beyond a reasonable doubt, every fact essential to the conviction of the defendants . . .'. Thereafter, counsel for the United States suggested to the court that it might explain to the jury 'the question of reasonable doubt, eliminate the words "preponderance of the evidence" and stick to "reasonable doubt"'. The court said to the jury in response to this suggestion, 'The question of reasonable doubt is the question that you are to determine. If you are satisfied beyond a reasonable doubt that in the first count of the information that there was an adulteration, that is sufficient; if you are satisfied on the second count beyond a reasonable doubt that this was misbranded, that is sufficient. Does that answer your question?—*that is the preponderance of the evidence.*'¹⁴

"We are of the opinion that viewed as a whole the charge respecting the necessity of the jury finding that the proof offered by the United States was sufficient to prove the defendants' guilt beyond a reasonable doubt, was not clear. The learned trial judge had probably cured the original defects of the charge in this respect until he added the final clause italicized above, 'that is the preponderance of the evidence.' This so confused what he had stated previously that, in our opinion, the jury may well have been misled. Under all the circumstances the charge must be deemed to have been erroneous in this respect. Compare the circumstances of *Pomerantz v. United States*, 3 Cir., 51 F. 2d 911, and of *Thompson v. United States*, 3 Cir., 283 F. 895. The defendants in a criminal case are entitled to a clear and unequivocal charge

¹⁴ Italics added.

by the court that the guilt of the defendants must be proved beyond a reasonable doubt.

"In this connection we deem it desirable to call attention to Rule 30 of the Federal Rules of Criminal Procedure, 18 U. S. C. A., foll. Section 687 (Supp. 1946), which provides, *inter alia*, that, "The court shall inform counsel of its proposed action upon the requests [for charge] prior to their arguments to the jury . . ." We cannot say that the error in the charge respecting reasonable doubt would not have occurred had the trial court followed the provisions of Rule 30 and, therefore, we may not say that the defendants were prejudiced by the failure of the trial court to observe the rule. It is possible and even probable, however, that had the provisions of Rule 30 been observed, the court below might not have fallen into error in its charge respecting reasonable doubt. The provisions of the Criminal Rules should be observed.

"Another matter respecting the charge remains for consideration. As we have stated, there are three defendants and there are two counts in the indictment. The jury did not render separate verdicts as to the individual defendants in respect to their guilt on *each* of the two counts. The court did not charge the jury that they should find the respective defendants guilty or not guilty on *each* count of the information. That the jury did not render separate verdicts as to the guilt or innocence of the defendants on each of the two counts is demonstrated by the transcript of what took place in the court room upon the return of the jury with the verdicts. In other words, the jury found all of the defendants guilty without differentiation as to each count. The court then sentenced the defendants, as demonstrated by the respective judgments of conviction and the commitments, without differentiation as to the counts, imposing the respective sentences set out at an earlier point in this opinion.

"The error of the course pursued is, we think, immediately demonstrable by assuming a case in which the appellate tribunal sets aside a judgment of conviction or directs a verdict of acquittal on one of two counts of an indictment or information, the defendant having been found guilty on both counts and sentence having been imposed without regard to the separate counts. Under such circumstances how can the single sentence run against the defendant? He received one sentence on two counts. But the appellate tribunal found that there was enough evidence to support a conviction based on one count and that the trial court had properly charged the jury as to the law respecting that count; whereas, it found that though the evidence was sufficient to support the offense laid in the other count, the trial court had not properly charged the jury respecting the law applicable to that count. Under such circumstances a new trial would be necessary for upon remand the court below could not distinguish between the general verdict of the jury applicable to both counts. To state the matter in other words we say that where there are separate counts in an indictment or information, there must be separate verdicts by the jury, under proper instructions from the court, as to the guilt or innocence of each defendant on each count if a judgment of conviction is to stand where there is error in the record affecting one or more of the counts. The failure of differentiation in the case at bar is not important since the errors of the charge require reversal as to both counts in any event. The practice of separate verdicts on separate counts should be adhered to by the district courts of this circuit where more than one count is contained in an indictment or information.

"The judgments of conviction will be reversed."

The case was retried upon the defendants' pleas of not guilty, and at the conclusion of the testimony on January 4, 1949, and upon motion made on behalf of the defendants, the court ordered that count 2 of the information be dismissed. On the same day, a verdict of guilty on count 1 of the information was returned by the jury.

A motion for a new trial was made on behalf of the defendants, and on February 9, 1949, such motion was denied. On June 2, 1949, the court imposed a fine of \$1 against the company, \$100 against defendant Roach, and \$150 against defendant Lambert. Imposition of prison sentences against the individuals was suspended, and the individuals were placed on probation for 1 year.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2757. Adulteration of Peptulcyl Ampoules. U. S. v. Solex Laboratories, Inc., and Nicholas Raimondi. Pleas of guilty. Fine of \$1,000 against corporation and \$750 against individual. (F. D. C. No. 21433. Sample No. 20284-H.)

INFORMATION FILED: March 17, 1947, Eastern District of New York, against Solex Laboratories, Inc., Brooklyn, N. Y., and Nicholas Raimondi, president of the corporation.

ALLEGED SHIPMENT: On or about April 18, 1945, from the State of New York into the State of Oklahoma.

LABEL, IN PART: (Carton) "Sterile Intramuscular Solution Peptulcyl Ampoules Formula A neutral solution of: Proteolytic Enzymes"; (ampul) "Peptulcyl Proteolytic Enzymes."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it was represented to be sterile and to be suitable and appropriate for intramuscular injection, a use which requires a sterile product, whereas the article was not sterile and was unsuitable and inappropriate for intramuscular injection since it was contaminated with viable micro-organisms.

DISPOSITION: October 28, 1948. Pleas of guilty having been entered, the court imposed a fine of \$1,000 against the corporation and a fine of \$750 against the individual.

2758. Adulteration and misbranding of Obeto, Estrovar, and theobromine compound. U. S. v. Kenneth G. Ziegler (Ziegler Pharmacal Co.). Plea of guilty. Fine of \$300 on each of 10 counts, plus suspended fine of \$500 and suspended sentence of 1 year's imprisonment on each of remaining 2 counts. Defendant placed on probation for 1 year. (F. D. C. No. 25618. Sample Nos. 4894-K, 6105-K, 6361-K, 12967-K, 19271-K, 27405-K.)

INFORMATION FILED: March 11, 1949, Western District of New York, against Kenneth G. Ziegler, a member of the partnership of the Ziegler Pharmacal Co., Buffalo, N. Y.

ALLEGED SHIPMENT: On or about January 6, February 5, and March 11, 15, and 18, 1948, from the State of New York into the States of Massachusetts, Pennsylvania, Ohio, and Missouri.

NATURE OF CHARGE: *Obeto*. Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess. The article purported and was represented to be suitable and appropriate for intramuscular use, which use requires a sterile product, whereas it was not suitable and appropriate for such use since it was not sterile but was contaminated with viable micro-organisms. Misbranding, Section 502 (a), the label statements "Intramuscular" and "For intramuscular use" were false and misleading.

Estrovar. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess. The article purported and was represented to contain in each cubic centimeter estrogenic substance possessing a physiological activity equivalent to 10,000 International Units of estrone, whereas each cubic centimeter of the article contained estrogenic substance possessing a physiological activity equivalent to less than 10,000 International Units of estrone. Misbranding, Section 502 (a), the label statement "Each cc. contains Estrogenic Substance principally Estrone equivalent to 10,000 international units," was false and misleading.

Theobromine compound. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess. The article was represented to contain $\frac{1}{2}$ grain of phenobarbital per tablet but contained less than that amount of phenobarbital. Misbranding, Section 502 (a), the label statement "Tablets * * * Theobromine (Compound) * * * Phenobarbital $\frac{1}{2}$ gr." was false and misleading.

DISPOSITION: May 2, 1949. A plea of guilty having been entered, the court imposed a fine of \$300 on each of 10 counts of the information, plus a suspended fine of \$500 and a suspended sentence of 1 year's imprisonment on each of the remaining 2 counts, and placed the defendant on probation for 1 year.

2759. Adulteration and misbranding of tincture of green soap. U. S. v. 87 Cases
* * *. (F. D. C. No. 25706. Sample No. 43460-K.)

LABEL FILED: October 25, 1948, Northern District of Illinois.

ALLEGED SHIPMENT: On or about July 14, 1948, by Bri-Test, Inc., from New York, N. Y.

PRODUCT: 87 cases, each containing 24 1-pint bottles, of *tincture of green soap* at Broadview, Ill. Analysis showed that the product contained 30 percent isopropyl alcohol.

LABEL, IN PART: "Bri-Test U. S. P. Tincture of Green Soap (Green Soap Liniment)."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), an article containing isopropyl alcohol had been substituted in whole or in part for "U. S. P. Tincture of Green Soap," which the article purported to be, and which contains ethyl alcohol.

Misbranding, Section 502 (a), the name "U. S. P. Tincture of Green Soap (Green Soap Liniment)" was false and misleading as applied to an article that was not "U. S. P. Tincture of Green Soap."

DISPOSITION: May 10, 1949. Default decree of condemnation. The product was ordered delivered to a charitable institution, to be used for industrial or cleaning purposes.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2760. Misbranding of sulfur and cream tartar tablets. U. S. v. The Roosa & Ratliff Chemical Co. and John P. Roosa. Pleas of guilty. Fine of \$100 against each defendant. (F. D. C. No. 25600. Sample No. 19432-K.)

INFORMATION FILED: January 12, 1949, Southern District of Ohio, against the Roosa & Ratliff Chemical Co., a corporation, Cincinnati, Ohio, and John P. Roosa, president of the corporation.

ALLEGED SHIPMENT: On or about March 11, 1948, from the State of Ohio into the State of Indiana.

LABEL, IN PART: "R. & R. Sulphur and Cream Tartar Tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. These statements represented and suggested that the article possessed blood purifying properties; that it would purify the blood and would remove humors and other accumulations from the system due to sedentary life; and that it was of value in the treatment of chronic rheumatism and gout. The article did not possess blood purifying properties, and it would not be efficacious for the purposes represented.

DISPOSITION: February 4, 1949. Pleas of guilty having been entered, the court imposed a fine of \$100 against each defendant.

2761. Misbranding of blood tonic and herb tonic. U. S. v. George W. Finnell. Plea of guilty. Imposition of sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 25619. Sample Nos. 15165-K, 15938-K, 18497-K.)

INFORMATION FILED: March 15, 1949, Eastern District of Tennessee, against George W. Finnell, Decatur, Tenn.

ALLEGED SHIPMENT: On or about February 24, March 25, and April 13, 1948, from the State of Tennessee into the States of Michigan and Ohio.

PRODUCT: Analyses disclosed that the *blood tonic* was an aqueous solution of potassium iodide with a trace of an iron compound, and that the *herb tonic* was an aqueous extract and suspension of plant materials containing emodin.

LABEL, IN PART: "G. W. Finnell's Blood Tonic Dr. E. B. Gates' Prescription Contains Iron and Potassium Iodide" and "Finnell's Herb Tonic (Dr. E. B. Gates' Prescription) * * * Compounded of Rheum Palmatum, Faso Bark, Yellow Puccoon, Gall Weed, Century Plant, Phytolacca, Sarsaparilla, with 5% Salicylic Acid."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading. The statements represented and suggested that the *blood tonic* would act as a tonic for the blood and that the *herb tonic* possessed tonic properties and would be efficacious in the cure, mitigation, and treatment of diseases of the stomach, kidneys, and liver. The *blood tonic* would not act as a tonic for the blood, and the *herb tonic* did not possess tonic properties and would not be efficacious for the purposes represented.

*See also Nos. 2752, 2755, 2758, 2759.

DISPOSITION: April 22, 1949. A plea of guilty having been entered, the court suspended the imposition of sentence and placed the defendant on probation for two years. As a special condition of the probation, it was ordered that the defendant should not dispense any medicines either locally or interstate.

2762. Misbranding of Amends Solution, Primal Minerals, and Primal Vitamins.

U. S. v. Roy O. Wickham. Plea of *nolo contendere*. Sentence of 1 year's imprisonment; sentence suspended and defendant placed on probation.

(F. D. C. No. 24229. Sample Nos. 17288-H, 69860-H, 69861-H.)

INFORMATION FILED: April 20, 1948, Northern District of Indiana, against Roy O. Wickham, Mishawaka, Ind.

ALLEGED SHIPMENT: On or about June 15 and October 24, 1946, from the State of Indiana into the State of Illinois.

PRODUCT: Analyses showed that the *Amends Solution* consisted essentially of water and small amounts of potassium iodide, iodine, and organic material; and that the *Primal Minerals* consisted essentially of white compressed tablets containing calcium, phosphorus, iron, and iodine.

LABEL, IN PART: "Amends Solution," "Primal Minerals * * * Tablets * * * Ingredients: Dicalcium Phosphate, Iron and Ammonium Citrate, Copper Peptonate, Manganese Hypophosphate, Potassium Iodide, Zinc Citrate, Magnesium Oxide, and Potassium Iodide," and "Primal Vitamins * * * Capsules * * * Vitamins A, B, C, D, G, and Niacin Amide. Ingredients: Fish Liver Oil, Irradiated Ergosterol, Thiamin Hydrochloride, Riboflavin, Ascorbic Acid, and Niacin Amide."

NATURE OF CHARGE: *Amends Solution*. Misbranding, Section 502 (a), the labeling, which included accompanying letters relating to the article, was false and misleading. The labeling represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of arthritis and rheumatism. The article would not be efficacious for such purposes. Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label bore no statement of the active ingredients of the article.

Primal Minerals and *Primal Vitamins*. Misbranding, Section 502 (a), the labeling, which included accompanying letters relating to the articles, was false and misleading. The labeling represented and suggested that the articles in combination with each other would be efficacious in the cure, mitigation, and treatment of rheumatism and arthritis; that they would relieve pain and discomfort; and that they would be efficacious in restoring health, physical well-being, and happiness. The articles in combination with each other would not be efficacious for such purposes.

DISPOSITION: May 17, 1949. A plea of *nolo contendere* having been entered, the court imposed a sentence of 1 year's imprisonment. The sentence was suspended, and the defendant was placed on probation for 2½ years.

2763. Misbranding of Autry's Minerals. U. S. v. Natural Minerals Co. Plea of *nolo contendere*. Fine, \$250. (F. D. C. No. 25626. Sample No. 7670-K.)

INFORMATION FILED: April 8, 1949, Southern District of California, against the Natural Minerals Co., a corporation, Los Angeles, Calif.

ALLEGED SHIPMENT: On or about August 2, 1948, from the State of California into the State of New York.

LABEL, IN PART: "Autri's Minerals * * * Ingredients: Dicalcium Phosphate, Ferrous (Iron) sulphate, Potassium iodide and a natural sedimentary Mineral deposit consisting essentially of carbonebus material and the oxides of silicon with small amounts of other mineral oxides with excipients and sugar coating."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, which included a number of booklets entitled "Is Your Romance Dated?" "In Your Own Hands," and "A Portrait of Your Best Friend," were false and misleading since the article would not be efficacious for the purposes represented. The statements represented and suggested that the article would prevent failure of the glands of internal secretion, would retard old age, would make the body function properly as it should, and would restore normal vitality and youthful zest and pep; that it would prevent fatigue and permit the retention of all physical faculties to a greater age; that it would provide enchanting beauty; that it would prevent the face from becoming tired and drawn, would prevent signs of old age appearing at the age of thirty to thirty-five, would prevent wrinkles, would prevent the eyes from losing their luster, would prevent a dull and less animated facial expression, would prevent fingernails from becoming brittle and ridged, and would prevent poor health; that it would make the user well nourished and would improve the appearance; that it would overcome disease-producing factors and would provide richness and replenishment of the blood supply; that it would prevent infections; that it would keep the body in the best of health; that it would prevent numerous disturbances in the users' physical make-up, would prevent the gastrointestinal tract from losing the power to absorb in a normal way, and would prevent the cells of the body from losing the ability to assimilate; that it would give freedom from fatigue; that it would provide greater ability to work; and that it would improve the mind.

DISPOSITION: May 16, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$250.

2764. Misbranding of tooth paste. U. S. v. John J. Harris (No Equal Products Co.). Plea of guilty. Fine of \$100 and costs. (F. D. C. No. 23227. Sample Nos. 15354-H, 39540-H.)

INFORMATION FILED: January 14, 1948, Northern District of Illinois, against John J. Harris, trading as the No Equal Products Co., Chicago, Ill.

ALLEGED SHIPMENT: From the State of Illinois into the State of Wisconsin. The product was shipped on or about April 18, 1946, and February 6, 1947, and a number of booklets entitled "No Equal The World's Greatest Tooth Paste" were shipped on or about May 7, 1946, and February 17, 1947.

PRODUCT: Analysis showed that the product consisted of a gray paste containing essentially bentonite, water, calcium carbonate, a small amount of a fixed oil, and methyl salicylate.

LABEL, IN PART: "No Equal Tooth Paste."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklets were false and misleading since the article would not be effective for the purposes and would not fulfill the promises of benefit suggested and implied by the statements. The statements represented and suggested that the article would be effective in the treatment of rheumatic and pulmonary affections, disorders of the scrofulous, and eczematous type, abscesses, sores,

wounds, toothache, pyorrhea, mouth sores, bleeding gums, abscessed teeth, inflamed tonsils, sinus trouble, ulcerated and pus cases, irritation caused by artificial teeth, tongue blisters, swollen gums, sore throat, catarrh, and disorders of the mouth and throat; that the article would be effective in treating a dead and abscessed tooth where bone tissue had partly decayed; that it would be effective for healing and hardening tender and bleeding gums; that it would be effective in stopping toothache and in preventing and relieving pyorrheal conditions; that it would be effective in healing sunburn, infections, cuts, bruises, scalds, and insect and animal bites; that it would be effective in healing power in absorbing poisonous substances of the body and in relieving soreness and inflammation; that it would correct and prevent disorders, preserve the teeth and tissues, check ailments and stop pain, and relieve pain in the gums of teething infants.

Further misbranding, Section 502 (b) (2), the tubes containing the article bore no statement of the quantity of the contents.

DISPOSITION: October 13, 1948. A plea of guilty having been entered, the court imposed a fine of \$100 and costs.

2765. Misbranding of Spectro-Chrome. U. S. v. 1 Device * * *. (F. D. C. No. 17419. Sample No. 16673-H.)

LABEL FILED: September 29, 1945, Western District of Michigan.

ALLEGED SHIPMENT: By the Dinshah Spectro-Chrome Institute, from Newfield and Malaga, N. J. The device was shipped on or about August 21, 1945, and a quantity of printed and graphic matter was shipped on or about August 22, 1945.

PRODUCT: 1 *Spectro-Chrome* device at Houghton, Mich., together with a quantity of printed and graphic matter entitled "Favorscope for 1945," "Rational Food of Man," "Spectro-Chrome General Advice Chart for the Service of Mankind—Free Guidance Request," "Certificate of Benefit Studentship," "Spectro-Chrome—December 1941—Scarlet," "Spectro-Chrome Irradiation—Free Guidance," and "Spectro-Chrome Manual for Dinshah Spectro-Chrome."

The device consisted essentially of a cabinet equipped with an electric light bulb, an electric fan, a container for water, glass condenser lenses, and glass slides, each of a different color. The cabinet had an opening in the front in which the glass slides could be inserted and through which the light from the bulb would emit.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Dinshah Spectro-Chrome * * * Visible Spectrum Color Projector * * * This Spectro-Chrome Projector * * * is a Benefit granted to an Affiliate of Dinshah Spectro-Chrome Institute, a * * * Health Corporation * * * * * It is presented for self-use and self-verification" were false and misleading. These statements represented and suggested that the device was capable of restoring, maintaining, or otherwise favorably influencing the health of the user. The device was incapable of accomplishing the results claimed, and the use of colored light would have no effect on health.

Further misbranding, Section 502 (a), the statements and references in the printed and graphic matter accompanying the device were false and misleading. These statements represented and suggested that the device when used as directed was effective for the attainment, improvement, restoration, and maintenance of health. The device was not effective for such purposes,

and when used as directed, or in any manner whatsoever, may delay appropriate treatment of serious diseases, resulting in serious or permanent injury or death to the user.

DISPOSITION: Tyyne Helena Lindrus, Houghton, Mich., filed an answer to the libel, denying that the device was misbranded. Thereafter, on April 11, 1949, upon motion by the United States attorney, an order was entered directing the claimant to post security for costs, and providing that upon the claimant's failure to post such security, the Government might apply for an order of condemnation.

On May 23, 1949, upon the failure of the claimant to comply with the order of April 11, 1949, judgment of condemnation was entered and the device was ordered destroyed.

DRUGS FOR VETERINARY USE

2766. Adulteration and misbranding of *Avi-Green Drinking Water Tablets*.

U. S. v. 138 Bottles * * *. (F. D. C. No. 27025. Sample No. 1432-K.)

LIBEL FILED: April 25, 1949, Western District of North Carolina.

ALLEGED SHIPMENT: On or about April 10 and May 12, 1948, by the Anchor Serum Co., from South St. Joseph, Mo.

PRODUCT: 138 25-tablet bottles of *Avi-Green Drinking Water Tablets* at Charlotte, N. C.

LABEL, IN PART: "Avi-Green Drinking Water Tablets (Poultry Usage Only)
Each tablet contains: 3-Nitro-4-hydroxyphenylarsonic acid, 1.40 grs.; Ammonium Sulfocarbolate, 13.80 grs.; Sodium Sulfocarbolate, 13.80 grs., combined with Benzal Green in an inert and entirely soluble base. Manufactured by Pharmaceutical Division Anchor Serum Company South Saint Joseph, Missouri."

NATURE OF CHARGE: Adulteration, Section 501 (a) (4), the article contained a coal-tar color other than one from a batch that had been certified in accordance with the regulations.

Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading in that they represented and implied that the article was manufactured by the Anchor Serum Co. of South Saint Joseph, Mo., and that it was effective for disinfection of poultry drinking water and for the control of intestinal infections and intestinal parasites of poultry, whereas it was manufactured for the Anchor Serum Company by another firm and would not be effective for controlling infections and parasites generally of the intestines of poultry; Section 502 (b) (1), the label of the article failed to reveal the connection which the Anchor Serum Company had with the article; and, Section 502 (e) (2), the article was fabricated from two or more ingredients and its label failed to bear the common or usual name of the active ingredients since the ingredients of the article were declared in a manner which implied that three were active, whereas only one ingredient was active for the purposes recommended. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and methods and duration of administration in such manner and form as are necessary for the protection of users since the article contained organic arsenic and its label failed to warn against use in the drinking water of ducks, geese, and other waterfowl; and its label failed also to warn against use during the

five days preceding slaughter for human consumption. Further misbranding, Section 502 (j), the article was dangerous to the health of poultry when used in the dosage and with the duration prescribed, recommended, and suggested in its labeling, since it contained organic arsenic.

Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to such drug.

DISPOSITION: May 3, 1949. The Anchor Serum Co. having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered destroyed.

2767. Misbranding of Dr. Thompson's Hog Minerals, Dr. Thompson's Poultry Minerals, and Dr. Thompson's Intestinal Astringent. U. S. v. 31 Bags, etc. (F. D. C. No. 27005. Sample Nos. 25590-K to 25592-K, incl.)

LABEL FILED: April 18, 1949, Northern District of Iowa.

ALLEGED SHIPMENT: By the A. W. Thompson Co., from Prairie du Chien, Wis. The products were shipped on or about December 24, 1948, and February 21 and March 4 and 9, 1949, and a number of circulars were shipped between September and December 1948.

PRODUCT: 31 100-pound bags of *Dr. Thompson's Hog Minerals*, 1 100-pound bag of *Dr. Thompson's Poultry Minerals*, and 6 1-pound cans of *Dr. Thompson's Intestinal Astringent* at New Hampton, Iowa, together with a number of circulars entitled "Why Thompson's Mineral Feeds?" "What Others Say about Thompson's," and "Directions For Using Dr. Thompson's Intestinal Astringent For Hogs."

The labels of the products stated that the *Dr. Thompson's Hog Minerals* consisted of sterilized bone flour, bone black (spent), dicalcium phosphate, sodium sulfate, calcium carbonate, potassium chloride, iron sulfate, wood charcoal, sodium bicarbonate, iron oxide, anise seed, molasses, sulfur, and potassium iodide; that the *Dr. Thompson's Poultry Minerals* contained sterilized bone flour, dicalcium phosphate, bone derived calcium sulfate, bone black (spent), wood charcoal, calcium carbonate, sulfur, iron sulfate, star anise seed, sodium sulfate, iron oxide, and potassium iodide; and that the *Dr. Thompson's Intestinal Astringent* contained gum catechu, bicarbonate of soda, magnesium sulfate, copper sulfate, capsicum, licorice root, methylene blue, sulfate of iron, charcoal, potassium iodide, anise seed, and potassium dichromate.

LABEL, IN PART: "Dr. Thompson's Mineral Feeds Hog Minerals [or "Poultry Minerals"]" and "Dr. Thompson's Intestinal Astringent."

NATURE OF CHARGE: *Dr. Thompson's Hog Minerals* and *Dr. Thompson's Poultry Minerals*. Misbranding, Section 502 (a), the labeling of the articles was false and misleading since they were not capable of fulfilling the promises of benefit and therapeutic value implied by the labeling. The labeling represented and suggested that the articles would build bone, prevent rickets, aid coagulation of the blood, give firmness of blood and of muscles, aid and regulate heart action, help to digest fats, form shells of eggs, neutralize acidity of body fluids, regulate nerve stimulation, assist in regulating all body secretions, check infestation of internal parasites such as worms, improve the condition of skin and hair, assist in digestive regulation, purify the blood by stimulating circulation, increase red blood corpuscles, tone up membranes to greatest activity, assist digestion, help prevent intestinal putrefaction, improve the condition of the blood and appetite, retard parasitic infestation and growth internally of

worms, improve the appetite, tone and heal inflamed conditions in the intestines caused by worms, stimulate the kidneys, act to cleanse the animal body of impurities, purify the blood indirectly by stimulating the intestinal organs to carry off poisonous wastes, act as a tonic to the blood and tone up blood corpuscles, and aid in preventing indigestion; that the articles were excellent for anemic conditions; that they were antiseptic and would retard internal germ growth; that they would deodorize and check acid conditions in the digestive tract; that when used internally with sulfur, they were excellent in promoting healthy skin and building blood; that they would check gas formation, diarrhea, and scours; that they were useful in indigestion and dyspepsia; that they were antidotes to poisonous acids and were efficacious in checking gastric and intestinal indigestion; that they would check abnormal acidity, increase the flow of bile and gastric juice in the stomach, act chiefly on body glands, destroy germ life internally, reduce swellings and glandular growths, and make livestock and poultry thriftier and healthier; that the *Dr. Thompson's Hog Minerals* would be efficacious in the cure, mitigation, and treatment of abortion and retained afterbirth trouble in cows; that the *Dr. Thompson's Hog Minerals* would keep pigs healthy and gaining without a setback, bring hogs back on their feet, and be effective in the treatment of scours in hogs; and that the *Dr. Thompson's Poultry Minerals* would increase egg production, reduce chick losses from diarrhea, germ infection, and worms, make healthier poultry with more vitality and brighter appearance, make chicks grow faster, make stronger shells and larger and more uniform eggs, make more fertile eggs, and decrease loss of baby chicks.

Further misbranding, Section 502 (a), the labeling of the *Dr. Thompson's Hog Minerals* and the *Dr. Thompson's Poultry Minerals* was false and misleading since it represented and suggested that the articles consisted of minerals, whereas the *Dr. Thompson's Hog Minerals* contained the nonmineral ingredients, wood charcoal, anise seed, and molasses; the *Dr. Thompson's Poultry Minerals* contained the nonmineral ingredients, wood charcoal and star anise seed; and the labeling of the *Dr. Thompson's Poultry Minerals* was false and misleading since it represented and suggested that a product known as "Dr. Thompsons Intesepto" would be efficacious in the treatment of white diarrhea in baby chicks, whereas this product would not be efficacious for that purpose.

Dr. Thompson's Intestinal Astringent. Misbranding, Section 502 (a), the labeling of the article was false and misleading since it represented and suggested that the article was an intestinal astringent constituting an effective treatment for serious disease conditions of the intestinal tract of swine, calves, and colts; and that the article was effective as a general tonic for hogs that do not eat. The article was not effective for such purposes.

DISPOSITION: May 17, 1949. Default decree of condemnation and destruction.

2768. Misbranding of Ballum. U. S. v. 37 Cartons * * *. (F. D. C. No. 26965. Sample No. 1096-K.)

LIBEL FILED: April 7, 1949, Southern District of Florida.

ALLEGED SHIPMENT: On or about February 1, 1949, by the Savoy Drug & Chemical Co., from Chicago, Ill.

PRODUCT: 37 shipping cartons each containing 24 unit packages, and each unit package containing 2 bottles of *Ballum* and a leaflet at Miami Springs, Fla.

LABEL, IN PART: "Ballum—The Easy Way A Combination Worm and Physic Ball Active Ingredients—phenothiazine. 12 grams per oz."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflet were false and misleading. These statements represented and suggested that the article when used as directed would keep the intestines of horses free from the larvae of a certain variety of the strongyle; that it would be effective in removing "ascaroids" or large roundworms from the intestines of horses, and lung worms from horses; and that intestinal parasites destroy more horses than all other ailments combined. The article would not be effective for the purposes represented, and intestinal parasites do not destroy more horses than all other ailments combined.

DISPOSITION: May 4, 1949. G. E. Lewis, Miami Springs, Fla., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for the destruction of the leaflets and the relabeling of the product, under the supervision of the Federal Security Agency.

2769. Misbranding of Gwycam. U. S. v. 2 Bottles, etc. (F. D. C. No. 27157. Sample No. 25838-K.)

LABEL FILED: April 25, 1949, Northern District of Iowa.

ALLEGED SHIPMENT: On or about October 29, 1948, and February 7, 1949, from Kansas City, Mo.

PRODUCT: 2 1-gallon bottles, 6 32-ounce bottles, and 12 16-ounce bottles of *Gwycam* at Sioux City, Iowa, in the possession of the Midwest Products. The product, which had been shipped in bulk, was repackaged and labeled by the consignee.

LABEL, IN PART: "Active Ingredients: Guaiacol . . . 8.00%, Oil Eucalyptus . . . 5.00%, Cresol . . . 2.50%, Gum Camphor . . . 75%, Inert Ingredients: Emulsified Paraffin Oil . . . 83.75%."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "May be used as an aid for treating simple colds of Livestock and Poultry" was false and misleading since the product when used as directed was not effective as an aid for treating simple colds of livestock and poultry. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 25, 1949. Default decree of condemnation and destruction.

2770. Misbranding of International Pig and Sow Meal and International Hog Balancer. U. S. v. 42 Bags, etc. (F. D. C. No. 27009. Sample Nos. 45217-K, 45218-K.)

LABEL FILED: April 19, 1949, Northern District of Iowa.

ALLEGED SHIPMENT: On or about January 20, 1949, by the International Sugar Feed Co., from Minneapolis, Minn.

PRODUCT: 42 100-pound bags of *International Pig and Sow Meal* and 370 100-pound bags of *International Hog Balancer* at Klemme, Iowa, together with a number of circulars entitled "International Pig and Sow Meal" and "Feed International" which were received by the consignee from the shipper of the product during January or February 1949.

LABEL, IN PART: (Tag) "International Hog Balancer * * * Ingredients Soybean Oil Meal, Linseed Oil Meal, Tankage, Fish Meal, Wheat Flour Middlings, Standard Middlings, Gentian, Foenugreek, Epsom Salts, Special Steamed Bone Meal, Calcium Carbonate, Iron Oxide, Copper Sulphate, Sodium Bicarbonate, Manganese Sulphate, Spent Bone Black, Salt, Charcoal, Sulphur,

Potassium Iodide, Wheat Germ Meal, Irradiated Brewers' Type Yeast, Vitamin A and D Feeding Oil, Molasses. Contains not more than 5% of added minerals" and "International Pig and Sow Meal Ingredients Soybean Oil Meal, Linseed Oil Meal, Tankage, Fish Meal, Standard Middlings, Wheat Flour Middlings, Gentian, Foenugreek, Epsom Salts, Special Steamed Bone Meal, Calcium Carbonate, Iron Oxide, Copper Sulphate, Sodium Bicarbonate, Manganese Sulphate, Spent Bone Black, Salt, Charcoal, Sulphur, Potassium Iodide, Wheat Germ Meal, Irradiated Brewers' Type Yeast, Vitamin A and D Feeding Oil, Molasses."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the articles were false and misleading since the statements represented and suggested that the articles were capable of fulfilling the promises of beneficial results and therapeutic value, which they were not capable of effectively fulfilling: *International Pig and Sow Meal* "* * * carry pigs safely through the critical periods of early life. It helps prevent scours and promotes resistance to disease * * * (Digestive Stimulants) which aid digestion and assimilation. * * * many digestive disorders which may cause early death * * * it helps overcome these early digestive disorders * * * large litters and healthier pigs * * *" and *International Hog Balancer* "* * * (Digestive Stimulants) * * * feed consumed is more completely digested * * * Conditioning Ingredients * * * International Hog Balancer should be fed during pregnancy as its use will insure strong, well-formed pigs at birth. Its use should be continued during the suckling period so as to insure a good flow of milk for the young."

DISPOSITION: May 5, 1949. The International Sugar Feed Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

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¹⁵ (2756) Prosecution contested. Contains opinion of the court.

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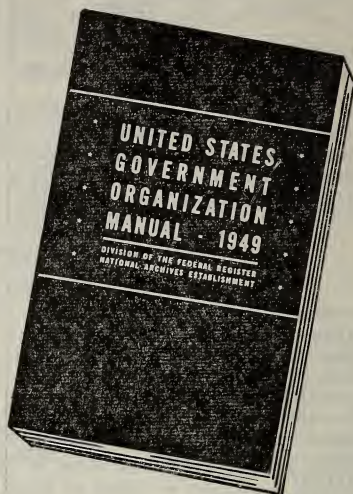
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¹⁵ (2756) Prosecution contested. Contains opinion of the court.

MANUFACTURER—PRODUCER—BANKER—LAWYER
TEACHER—STUDENT—AVERAGE CITIZEN

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The Courts
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National Military
Establishment
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Food and Drug
Administration
General Services
Administration



Housing and Home
Finance Agency
Selective Service System
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INFORMATION about these and other Federal departments and agencies is to be found in the 1949 *United States Government Organization Manual*, an authoritative 725-page handbook covering the legislative, executive, and judicial branches of the Government. Issued annually by the Division of the Federal Register, the National Archives Establishment, General Services Administration.

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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2771-2790

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., February 6, 1950.

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*For cosmetic, subject to the drug provisions of the Act, see No. 2781

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2771. Adulteration of Acid Iron Earth Water and Geo-Mineral. U. S. v. 6 Barrels, etc. (F. D. C. No. 26927. Sample Nos. 45975-K, 45976-K.)

LIBEL FILED: April 12, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about March 15, 1949, by W. L. Newcomb, from Bay Springs, Miss.

PRODUCT: 6 50-gallon barrels of *Acid Iron Earth Water*, 2 tanks containing a water-dilution of material from the barrels, and a number of bottles of *Geo-Mineral*, which contained also a water-dilution of material from the aforesaid barrels, at St. Louis, Mo.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

DISPOSITION: May 5, 1949. Default decree of condemnation and destruction.

2772. Adulteration of Chinese rhubarb root. U. S. v. 5 Bags * * *. (F. D. C. No. 26515. Sample No. 51234-K.)

LIBEL FILED: February 11, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: On or about June 3, 1948, from New York, N. Y.

PRODUCT: 5 100-pound bags of *Chinese rhubarb root* at Columbus, Ohio.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects and insect fragments. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: March 24, 1949. Default decree of destruction.

2773. Adulteration of valerian root. U. S. v. 12 Bags * * *. (F. D. C. No. 26248. Sample No. 51227-K.)

LIBEL FILED: January 4, 1949, Southern District of Indiana.

ALLEGED SHIPMENT: On or about March 14, 1947, from Brooklyn, N. Y.

PRODUCT: 12 bags, each containing approximately 118 pounds, of *valerian root* at Indianapolis, Ind.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the product consisted in whole or in part of a filthy substance by reason of the presence of insects and insect parts. The product was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: March 24, 1949. Default decree of forfeiture and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2774. Adulteration and misbranding of Neo-Lixir and adulteration of So-Lix-Co. U. S. v. St. Louis Physicians Supply Co. and Leo D. Lillie. Pleas of guilty. Fine of \$300 against each defendant. (F. D. C. No. 25621. Sample Nos. 26245-K, 26252-K.)

INFORMATION FILED: March 24, 1949, Eastern District of Missouri, against the St. Louis Physicians Supply Co., a corporation, St. Louis, Mo., and Leo D. Lillie, president of the corporation.

*See also Nos. 2788, 2789.

ALLEGED SHIPMENT: On or about March 5 and 9, 1948, from the State of Missouri into the States of Iowa and Illinois.

NATURE OF CHARGE: *Neo-Lixir*. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, in that each fluid ounce of the article purported and was represented to contain 4 grains of U. S. P. Reference Pepsin, whereas each fluid ounce of the article contained less than 4 grains of U. S. P. Reference Pepsin. Misbranding, Section 502 (a), the label statement "Each Fluid Ounce Contains 4 grains U. S. P. Reference Pepsin" was false and misleading.

So-Lix-Co. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each fluid ounce purported and was represented to contain 40 grains of salicylic acid (as sodium salicylate), whereas it contained less than that amount of salicylic acid (as sodium salicylate).

DISPOSITION: April 7, 1949. Pleas of guilty having been entered, the court imposed a fine of \$300 against each defendant.

2775. Adulteration and misbranding of estrogenic substance. U. S. v. Gregory S. Brooks and Intramed Co., Inc. Motion denied for dismissal of information. Pleas of guilty. Fine of \$200 against corporation. Fine of \$200 and sentence of 1 year in jail against individual; jail sentence suspended and individual placed on probation for 1 day. (F. D. C. No. 24233. Sample No. 45060-H.)

INFORMATION FILED: March 22, 1949, Southern District of New York, against the Intramed Co., Inc., New York, N. Y., and Gregory S. Brooks, president of the corporation.

ALLEGED SHIPMENT: On or about April 17, 1946, from the State of New York into the State of California.

LABEL, IN PART: "2000 cc Natural Whole Estrogenic Substance In Sesame Oil Consisting Principally of Estrone and Such Other Auxiliary Hormones As Are Normally Present In Gravid Mares' Urine Each 1 cc is Equivalent to 20,000 I. U. Rated as Estrone."

NATURE OF CHARGE: Adulteration, Section 501 (b) (2), estradiol had been substituted in part for natural whole estrogenic substance in sesame oil.

Misbranding, Section 502 (a), the label of the article was false and misleading since the article was not "Natural Whole Estrogenic Substance In Sesame Oil Consisting Principally of Estrone and Such Other Auxiliary Hormones As Are Normally Present In Gravid Mares' Urine."

DISPOSITION: A motion to dismiss the information was filed on behalf of the defendants, alleging as grounds for such dismissal that the defendants had received the article in interstate commerce and made delivery in good faith; and that a letter received from the supplier which contained, among other things, the representation that the product may be labeled "Natural Whole Estrogenic Substance, as derived from Gravid Mares' Urine," constituted a guaranty. The Government, in its reply, denied those allegations; and, in addition, it alleged that if the letter did constitute a guaranty as contemplated by the Act, that the defendants had exceeded its terms in labeling the product as aforesaid.

On May 16, 1949, the court denied the defendants' motion without prejudice, basing the denial not on the question of law but because the facts alleged in defendants' motion had not been proved or stipulated. Pleas of guilty were

entered on behalf of both defendants on June 8, 1949, and the court sentenced each defendant to pay a fine of \$200. The individual defendant, Gregory S. Brooks, also received a sentence of 1 year in jail which, however, was suspended, and he was placed on probation for 1 day.

2776. Adulteration and misbranding of posterior pituitary injection. U. S. v. 72 Ampuls * * *. (F. D. C. No. 27172. Sample No. 58105-K.)

LABEL FILED: April 27, 1949, District of Arizona.

ALLEGED SHIPMENT: On or about February 18, 1949, by E. S. Miller Laboratories, Inc., from Los Angeles, Calif.

PRODUCT: 72 1-cc. ampuls of *posterior pituitary injection* at Phoenix, Ariz. Analysis showed that the potency of the product was less than the potency specified by the United States Pharmacopoeia.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Posterior Pituitary Injection," a drug the name of which is recognized in the United States Pharmacopoeia, and its strength differed from the official standard.

Misbranding, Section 502 (a), the label statement "(10 U. S. P. Units) per cc" was false and misleading as applied to the article, which contained less than 10 U. S. P. units of posterior pituitary per cubic centimeter.

DISPOSITION: June 23, 1949. Default decree of condemnation and destruction.

2777. Adulteration of sodium iodide injection. U. S. v. 11 Cartons * * *. (F. D. C. No. 26863. Sample No. 47081-K.)

LABEL FILED: March 16, 1949, Western District of New York.

ALLEGED SHIPMENT: On or about October 1, 1948, from Columbus, Ohio.

PRODUCT: 11 cartons, each containing 25 10-cc. ampuls, of *sodium iodide* at Buffalo, N. Y.

LABEL, IN PART: "Sodium Iodide—For Intravenous Administration Only."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, "Ampuls of Sodium Iodide," the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: April 13, 1949. Default decree of condemnation and destruction.

2778. Adulteration of Monocaine. U. S. v. 7,117 Boxes * * *. (F. D. C. No. 26560. Sample No. 33298-K.)

LABEL FILED: February 23, 1949, Southern District of California.

ALLEGED SHIPMENT: Between the approximate dates of February 20, 1943, and January 18, 1944, from Brooklyn, N. Y.

PRODUCT: 7,117 boxes of *Monocaine* at Fresno, Calif. Analysis showed that the epinephrine in the product had deteriorated to such an extent that practically none of its potency remained.

LABEL, IN PART: "Monocaine HCL Solution 1% with Epinephrin 1:75,000."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Epinephrin 1:75,000." The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: May 26, 1949. Default decree of condemnation and destruction.

2779. Adulteration and misbranding of Congo red. U. S. v. 176 Ampuls * * *.
(F. D. C. No. 26414. Sample No. 9097-K.)

LABEL FILED: January 24, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about July 23, 1948, by George A. Breon & Co., from Kansas City, Mo.

PRODUCT: 176 10-cc. ampuls of *Congo red* at Bronx, N. Y. Analysis showed that the product contained not more than 0.6 percent of *Congo red*.

LABEL, IN PART: "Sterile Solution Congo Red 1% W/V."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Congo Red 1%."

Misbranding, Section 502 (a), the label statement "Congo Red 1%" was false and misleading.

DISPOSITION: April 11, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2780. Alleged misbranding of Gramer's Sulgly-Minol. U. S. v. Walter W. Gramer. Plea of not guilty. Tried to the court. Defendant discharged and information dismissed. (F. D. C. No. 25586. Sample No. 24582-K.)

INFORMATION FILED: November 30, 1948, District of Minnesota, against Walter W. Gramer, Minneapolis, Minn.

ALLEGED SHIPMENT: On or about April 16, 1948, from the State of Minnesota into the State of Wisconsin.

PRODUCT: Analysis disclosed that the product was an orange-red alkaline aqueous solution containing essentially sulfur, lime, and glycerin.

LABEL, IN PART: "Gramer's Sulgly-Minol * * * Compounded and Developed by Walter W. Gramer, Minneapolis, Minnesota Distributor Fred J. Fasching 1110 Birch Street Eau Claire, Wis."

NATURE OF CHARGE: Misbranding, Section 502(a), certain statements on the label of the article and in accompanying circulars entitled "Arthritis It's Grip Broken" and "A Light Should Not Be Hidden" were false and misleading since the article would not fulfill the promises of benefit stated and implied. The statements represented and suggested that the article when applied to the soles of the feet before retiring, would be efficacious in the treatment of muscular pains; that it would be efficacious in the relief and in the treatment of arthritis; that it would be efficacious in the treatment of boils, acne, and ailments of a rheumatic nature; and that it would relieve one from the pains of arthritis and rheumatism and would take the stiffness and soreness out of one's legs and knees.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before the court without a jury. At the conclusion of the testimony, the court found that the Government had not sustained the burden of proof re-

*See also Nos. 2774-2776, 2779.

quired under the law in proving the allegations of the information; and on April 6, 1949, the case was concluded with the dismissal of the information and the discharge of the defendant.

2781. Misbranding of Alapex. U. S. v. 176 Bottles, etc. (F. D. C. No. 23701. Sample No. 99846-H.)

LIBEL FILED: On or about September 19, 1947, Western District of Missouri.

ALLEGED SHIPMENT: By Geoffrey Jordn, Inc., from Alliance, Ohio. The product was shipped on or about July 23, 1947, and a number of circulars were shipped on or about August 5, 1947.

PRODUCT: 176 4-ounce bottles of *Alapex* at Kansas City, Mo., together with a number of circulars entitled "Alapex for the Scalp." Examination showed that the product consisted essentially of alcohol, water, bichloride of mercury, and calomel.

NATURE OF CHARGE: Misbranding, Section 502(a), certain statements on the bottle labels and in the circulars were false and misleading. The statements represented and suggested that the article was effective in the treatment of falling hair, baldness, dandruff, and ringworm, whereas the article was not effective in the treatment of such conditions.

DISPOSITION: October 31, 1947. Default decree of destruction.

2782. Misbranding of Colusa Natural Oil and Colusa Natural Oil Capsules. U. S. v. 5 Bottles, etc. (F. D. C. No. 23161. Samples Nos. 86912-H, 86913-H.)

LIBEL FILED: June 2, 1947, Southern District of Iowa.

ALLEGED SHIPMENT: On or about April 28, 1947, by Joseph Ventura, from Chicago, Ill.

PRODUCT: 5 4-ounce bottles and 15 2-ounce bottles of *Colusa Natural Oil* and 7 200-capsule bottles and 30 100-capsule bottles of *Colusa Natural Oil Capsules* at Clinton, Iowa. Examination showed that the products consisted of crude petroleum oil.

LABEL, IN PART: (Bottle) "Colusa Natural Oil * * * Colusa Remedy Co. * * * Los Angeles, California."

NATURE OF CHARGE: Misbranding, Section 502(a), certain statements on the bottle labels were false and misleading. These statements represented and suggested that the articles, when taken individually or in combination, were effective in the treatment of psoriasis, eczema, leg ulcers, athlete's foot, and open sores, whereas the articles when taken as directed, were not effective for such purposes.

DISPOSITION: March 15, 1948. Default decree of condemnation and destruction.

2783. Misbranding of Nef-Tex Tablets. U. S. v. 28 Cartons * * *. (F. D. C. No. 27156. Sample No. 13116-K.)

LIBEL FILED: April 26, 1949, District of Delaware.

ALLEGED SHIPMENT: On or about November 18, 1948, by the Drexel Laboratories, from Drexel Hill, Pa.

PRODUCT: 28 cartons each containing a leaflet entitled "Nef-Tex Tablets" and a 48-tablet bottle of *Nef-Tex Tablets* at Wilmington, Del. Analysis showed that the product consisted essentially of oxyquinoline sulfate (1 grain per tablet), saccharin, methyl salicylate, and oil of peppermint.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article when used as directed was not effective to inhibit bacteria, arrest fermentation, and to remove the cause of intestinal and urinary irritations, and, further, it was not effective in the treatment of grippe and common colds: (Bottle label) “* * * They inhibit bacteria, arrest fermentation, removing cause of intestinal and urinary irritations” and (leaflet entitled “Nef-Tex Tablets”) “* * * Nef-Tex Tablets Recommended for Grippe and Common Cold Health authorities agree that a germ or virus is responsible for the common run of colds and that all of us should guard against them. If you are subject to colds or have trouble getting rid of a cold try Nef-Tex Tablets * * *.”

DISPOSITION: June 15, 1949. Default decree of condemnation and destruction.

2784. Misbranding of Prostall. U. S. v. 4 Bottles, etc. (F. D. C. No. 27163. Sample No. 29299-K.)

LABEL FILED: April 25, 1949, District of Colorado.

ALLEGED SHIPMENT: By Douglas Laboratories, Inc., from Boston, Mass. The product was shipped on or about April 6, 1949, and a number of pamphlets were shipped on or about March 1, 1949.

PRODUCT: 4 100-capsule bottles of *Prostall* at Denver, Colo., together with 18 pamphlets entitled “The Story of Prostall.” Analysis indicated that the product consisted of amino acids.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the pamphlets were false and misleading since they represented and suggested that the article was effective in the relief of pain and prostate hypertrophy, whereas the article was not effective for such purposes.

DISPOSITION: June 1, 1949. Default decree of condemnation and destruction.

2785. Misbranding of Vita Orange. U. S. v. 10 Cases, etc. (F. D. C. No. 26096. Sample Nos. 5308-K to 5310-K, incl.)

LABEL FILED: On or about December 1, 1948, District of Rhode Island.

ALLEGED SHIPMENT: On or about September 2 and 18, 1948, by the California Fruit Juice Co., from Waltham, Mass.

PRODUCT: 10 cases, each containing 12 quart bottles, 15 cases, each containing 6 half-gallon bottles, and 39 1-gallon bottles, of *Vita Orange* at Newport, R. I., together with a number of circulars entitled “The Good Morning to Health.”

Examination showed that the product was a mixture of orange juice, orange oil, water, acid, sugar, and artificial color, and that it contained approximately 5,000 U. S. P. units of vitamin C per one-half gallon.

LABEL, IN PART: (Bottle) “Vita Orange with Vitamins Added.”

NATURE OF CHARGE: Misbranding, Section 502 (a), the name “Vita Orange” and certain statements in the circulars were false and misleading since they represented and suggested that the article was nutritionally better than orange juice; that it was a better source of vitamins than orange juice; that it would be effective to promote health and healthy bones, teeth, and gums; and that it would be effective in the treatment of colds and prevention of infections. The article was not nutritionally better than orange juice; it was not a better source of vitamins than orange juice; and it would not be effective for the purposes represented.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: February 2, 1949. Default decree of condemnation. The circulars were ordered destroyed, and the product was ordered delivered to a charitable institution.

2786. Misbranding of vitamin E capsules. U. S. v. 111 Bottles * * *. (F. D. C. No. 26157. Sample No. 51226-K.)

LABEL FILED: December 22, 1948, Southern District of Ohio.

ALLEGED SHIPMENT: On or about November 19, 1948, from Detroit, Mich.

PRODUCT: 111 bottles, each containing 100 capsules, of *vitamin E* at Cincinnati, Ohio, in the possession of the Cincinnati Vitamin Co. A number of circulars entitled "Vitamin E and Heart Disease," which had been prepared by the consignee and printed locally, were on the counter in close proximity to the product. Examination indicated that the product had the composition stated on its label.

LABEL, IN PART: "100 Gelatin Capsules No. 153 Vitamin E Each Capsule Contains 30 mg. Alpha Tocopherol."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since they represented and suggested that the article was effective to prevent and cure heart disease, whereas the article was not effective for such purpose. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: February 23, 1949. Default decree of condemnation and destruction.

2787. Misbranding of Burnett's Radio-Active Emanator. U. S. v. 4 Devices * * *. (F. D. C. No. 23731. Sample No. 76470-H.)

LABEL FILED: On or about October 8, 1947, Southern District of Texas.

ALLEGED SHIPMENT: On or about July 11 and 30 and August 14, 1947, by W. H. Burnett, from Fordyce, Ark.

PRODUCT: 4 unlabeled devices at Monroe City, Tex. Examination showed that the device consisted of a molded concrete block containing a trace of radio-active material.

NATURE OF CHARGE: Misbranding, Section 502, the device was represented as "Burnett's Radio-Active Emanator," whereas it contained only a trace of radio-active material, which was too little to be of any therapeutic significance.

DISPOSITION: December 19, 1947. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE

2788. Adulteration and misbranding of Fox No. 1 Mineral Feed and misbranding of Poultrate, Vetrone, and Fox Triumph Swine Liquid. U. S. v. Foxbilt, Inc., and E. Frank Fox. Pleas of guilty. Fine of \$325 against each defendant, plus costs. (F. D. C. No. 25602. Sample Nos. 25384-K, 25385-K, 25387-K, 25389-K.)

INFORMATION FILED: February 24, 1949, Southern District of Iowa, against Foxbilt, Inc., Des Moines, Iowa, and E. Frank Fox, president of the corporation.

ALLEGED SHIPMENT: On or about August 15, 1947, and January 20 and April 9, 1948, from the State of Iowa into the State of Minnesota. A number of circulars entitled "How to Feed Fox No. 1 Mineral Feed" accompanied the *Fox No. 1 Mineral Feed*, and a number of booklets entitled "Calling All Hens" and "Foxbilt Feeds" accompanied the *Poultrate* and *Vetrone*, respectively.

LABEL, IN PART: "Fox No. 1 Mineral Feed * * * Guaranteed Analysis Calcium (Ca), Not more than 3.16%, Phosphorus, Not less than .50%, Iodine (I), Not less than .008%, Salt (NaCl), * * * None * * * Contains Sodium Bicarbonate, Sulphate Soda, Soft Phosphate with Colloidal Clay, American Wormseed, Poke Root, Sulphur (7½%), Potassium Nitrate, Iron Oxide, Iron Sulphate, Cascara, Mandrake, Charcoal (5%), Areca Nut, Pulverized Limestone (Containing 98% Calcium Carbonate), Manganese Sulphate, Potassium Iodide," "Poultrate * * * Guaranteed Analysis Protein, Not less than 25%, Fat, Not less than 3.5%, Calcium (Ca), Not more than 7.50%, Not less than 6%, Fiber, Not more than 6.5%, Phosphorus (P), Not less than 1.0%, Iodine (I), Not less than .01%, Salt (NaCl), Not less than 4.6%, N. F. E. Not less than 18.0%," "Vetrone * * * Contents Ferric Sulphate, Cobalt Sulphate, Magnesium Sulphate, Ferrous Sulphate, Manganese Sulphate, Aluminium Sulphate," "Fox Triumph Swine Liquid * * * Active Ingredients Thymol, Creosote, Soda Ash, Sodium Hydroxide (Caustic Soda), Salt * * * Inert Ingredients Glycerine, Oil of Anise, Licorice Root, Saccharin, Water."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the *Fox No. 1 Mineral Feed* differed from that which it was represented to possess since it was represented to contain not less than 0.5 percent of phosphorus and it contained less than that amount of phosphorus.

Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading since the articles would not be effective for the purposes represented and since the *Fox No. 1 Mineral Feed* contained less than the declared amount of phosphorus. The statements represented and suggested that the *Fox No. 1 Mineral Feed* contained not less than 0.5 percent of phosphorus and would be effective in the treatment of digestive disorders in shoats and gilts, in the conditioning of pigs and stock hogs, in the treatment of all types of unthrifty and backward conditions in hogs, in the treatment of pigs when they go off their feed, in the treatment of horses of all types in a weakened run-down condition, in the treatment of sheep which are out-of-condition, and in the treatment of poultry in a run-down condition; that the *Poultrate* would be effective in the prevention and treatment in poultry of coccidiosis, worms, cholera, typhoid, colds, roup, tuberculosis, and blackhead; that the *Vetrone* when used as directed would be effective in the prevention and treatment of diseases of poultry, hogs, and dairy cows, in the prevention and treatment in poultry of coccidiosis, parasites, cholera, and a run-down condition, in the prevention of anemia in pigs, and in the treatment of pig scours, necro, and mastitis; and that the *Fox Triumph Swine Liquid* when used as directed would be effective in the prevention and treatment of disease conditions in swine and in alkalizing the intestinal tract of swine.

The *Fox No. 1 Mineral Feed* was alleged to be adulterated and misbranded and the *Poultrate* and *Vetrone* were alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on food.

DISPOSITION: May 21, 1949. Pleas of guilty having been entered, the court imposed a fine of \$325 against each defendant, together with costs.

2789. Adulteration and misbranding of *Mocalcidx*. U. S. v. 35 Bottles, etc. (F. D. C. No. 27180. Sample No. 42728-K.)

LABEL FILED: May 6, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about August 4 and 16, 1948, from Kansas City, Kans., by the Missouri Valley Serum Co.

PRODUCT: 35 bottles of *Mocalcidx* at Chicago, Ill. Analysis showed that the product contained 0.51 gram of dextrose per 10 cc.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since it contained less than the declared amount of dextrose.

Misbranding, Section 502 (a), the label statement "1 gram dextrose per 10 cc" was false and misleading as applied to the product, which contained less than the stated amount of dextrose.

DISPOSITION: June 14, 1949. Default decree of condemnation and destruction.

2790. Misbranding of *Tim-Ball Solution*. U. S. v. 12 Bottles * * *. (F. D. C. No. 26966. Sample No. 30197-K.)

LABEL FILED: April 1, 1949, District of Arizona.

ALLEGED SHIPMENT: On or about February 5, 1949, by the *Tim-Ball Liniment Co.*, from Arcadia, Calif.

PRODUCT: 12 1-pint bottles of *Tim-Ball Solution* at Phoenix, Ariz. Analysis showed that the product consisted essentially of iodine, 3.15 percent; potassium iodide, 1.96 percent; alcohol, 55.6 percent; and water.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article and in the circular were false and misleading since they represented and suggested that the article would be effective in the treatment of disease conditions involving the legs of horses, whereas it was not effective for such purposes: (Label) "* * * Miracle Treatment for the Bad Leg Problem * * * Buck Shins, Big Knee * * * Swelling and Lameness * * * Osslets * * * Splints, Ringbone" and (accompanying circular) "* * * A Miracle Treatment For The Bad Leg Problem * * * *Tim-Ball Solution* * * * It Is Effective * * * It Goes To Work The Minute You Paint It On * * * Splints and Ringbone * * * Buck Shins * * * Sesimoid And Big Knee * * * Osslets."

DISPOSITION: May 24, 1949. Default decree of condemnation and destruction.

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Colusa Natural Oil and Colusa Natural Oil Capsules-----	2782	Gramer's Sulgly-Minol-----	¹ 2780
Congo red-----	2779	Hair and scalp preparation-----	2781
		Heart disease, remedy for-----	2786

¹ (2775, 2780) Prosecution contested.

	N. J. No.		N. J. No.
Injection preparations. <i>See</i> Parenteral drugs.		Radio-Active Emanator, Burnett's	2787
Mineral feed, Fox No. 1	2788	Rheumatism, remedy for	¹ 2780
Mocalcidex	2789	Rhubarb root, Chinese	2772
Monocaine	2778	Sodium iodide injection	2777
Nef-Tex Tablets	2783	So-Lix-Co	2774
Neo-Lixir	2774	Sulgly-Minol, Gramer's	¹ 2780
Parenteral drugs	¹ 2775-2779, 2789	Swine Liquid, Fox Triumph	2788
Pituitary, posterior, injection	2776	Tim-Ball Solution	2790
Posterior pituitary injection	2776	Valerian root	2773
Poultrate	2788	Veterinary preparations	2788-2790
Prostall	2784	Vetrone	2788
Prostate remedy	2784	Vita Orange	2785
		Vitamin preparation	2786

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N. J. No.		N. J. No.
Breon, George A., & Co.:		Foxbilt, Inc.:	
Congo red	2779	Fox No. 1 Mineral Feed,	
Brooks, G. S.:		Poultrate, Vetrone, and Fox	
estrogenic substance	¹ 2775	Triumph Swine Liquid	2788
Burnett, W. H.:		Geoffrey Jordn, Inc.:	
Burnett's Radio-Active Emanator	2787	Alapex	2781
California Fruit Juice Co.:		Gramer, W. W.:	
Vita Orange	2785	Gramer's Sulgly-Minol	¹ 2780
Cincinnati Vitamin Co.:		Intramed Co., Inc.:	
vitamin E capsules	2786	estrogenic substance	¹ 2775
Colusa Remedy Co.:		Lillie, L. D.:	
Colusa Natural Oil and Colusa		Neo-Lixir and So-Lix-Co	2774
Natural Oil Capsules	2782	Miller, E. S., Laboratories, Inc.:	
Douglas Laboratories, Inc.:		posterior pituitary injection	2776
Prostall	2784	Missouri Valley Serum Co.:	
Drexel Laboratories:		Mocalcidex	2789
Nef-Tex Tablets	2783	Newcomb, W. L.:	
Fasching, F. J.:		Acid Iron Earth Water and	
Gramer's Sulgly-Minol	2780	Geo-Mineral	2771
Fox, E. F.:		St. Louis Physicians Supply Co.:	
Fox No. 1 Mineral Feed,		Neo-Lixir and So-Lix-Co	2774
Poultrate, Vetrone, and Fox		Tim-Ball Liniment Co.:	
Triumph Swine Liquid	2788	Tim-Ball Solution	2790
		Ventura, Joseph:	
		Colusa Natural Oil and Colusa	
		Natural Oil Capsules	2782

¹ (2775, 2780) Prosecution contested.

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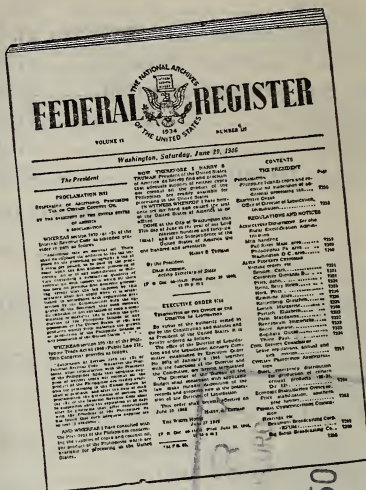
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FEDERAL SECURITY AGENCY**FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2791-2810

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., February 6, 1950.

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*For new drug filed without effective application, see No. 2791; omission of, or unsatisfactory, ingredients statements, Nos. 2794, 2810; failure to bear a label containing an accurate statement of the quantity of the contents, No. 2794; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2794; cosmetics, actionable under the drug provisions of the Act, Nos. 2803, 2804.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2791. Misbranding of syrup urethane. U. S. v. 94 Bottles * * * (and 1 other seizure action). (F. D. C. Nos. 26645, 26647. Sample Nos. 11186-11187-K.)

LIBELS FILED: On or about March 11 and 17, 1949, Eastern and Southern Districts of New York.

ALLEGED SHIPMENT: Between the approximate dates of November 29, 1948, and February 16, 1949, by Marvin R. Thompson, Inc., from Stamford, Conn.

PRODUCT: 94 16-ounce bottles and 12 1-gallon bottles of *syrup urethane* at Brooklyn and New York, N. Y.

LABEL, IN PART: "Syrup Urethane * * * Each teaspoonful (5-cc) contains urethane 4 Grs. in a flavored syrup base. Directions: 1 teaspoonful every 3 or 4 hours, or as directed by the physician."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in its labeling, namely, "1 teaspoonful every 3 or 4 hours." since the administration every 3 or 4 hours of 1 teaspoonful of the article containing the stated amount of urethane is capable of causing leucopenia.

Further misbranding, Section 505 (a), the article was a new drug within the meaning of the law, and an application filed pursuant to Section 505 (b) of the law was not effective with respect to the article.

DISPOSITION: April 22 and May 9, 1949. Default decrees of condemnation and destruction.

2792. Misbranding of vaginal suppositories. U. S. v. 34 Boxes * * *. (F. D. C. No. 27058. Sample Nos. 29261-K, 29262-K.)

LIBEL FILED: April 27, 1949, District of Colorado.

ALLEGED SHIPMENT: On or about October 28, 1946, and January 20, 1949, by the South Bend Remedy Co., from San Mateo, Calif.

PRODUCT: 34 boxes of *vaginal suppositories* at Denver, Colo. Examination of samples showed that each suppository contained not less than 36 percent of potassium alum.

LABEL, IN PART: "Magnolia Blossom 6 Vaginal Suppositories."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "For minor vaginal irritations" appearing on the label of a portion of the article was false and misleading since the article would not be effective in relieving irritations but would produce an irritation; and, Section 502 (j), the article was dangerous to health when used with the frequency or duration recommended or suggested in the labeling thereof, namely, "insert one suppository into the vagina * * * and leave undisturbed for seventy two hours."

DISPOSITION: June 1, 1949. Default decree of condemnation and destruction.

2793. Misbranding of Gattis' Worm Oil. U. S. v. 60 Bottles * * * (and 1 other seizure action). (F. D. C. Nos. 27002, 27003. Sample Nos. 1640-K, 1641-K.)

LIBELS FILED: April 14, 1949, Western District of North Carolina.

ALLEGED SHIPMENT: On or about January 5 and February 19, 1949, by the Gattis Chemical Co., from Nashville, Tenn.

PRODUCT: 186 bottles of *Gattis' Worm Oil* at Asheville, N. C. Analysis showed that the product had the composition stated on its label.

LABEL, IN PART: "Gattis' Worm Oil Each Fluid Ounce Contains: 22 Mins. Oil Worm Seed, 12 Mins. Chloroform, 421 Mins. Castor Oil, Turpentine, Combined with Aromatics. Directions: Children 2 to 5 years old, one-half teaspoonful; 5 to 10 years old, one teaspoonful. Adults, one and a half teaspoonfuls. One dose morning and night; (May be given for 2 or 3 days if necessary.) * * * Net Contents 1 Fl. Oz."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, or suggested in its labeling.

DISPOSITION: May 31, 1949. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2794. Misbranding of benzedrine sulfate tablets and benadryl hydrochloride kapseals. U. S. v. Harry Kaplan, pharmacist for Fienup's Drug Co. Plea of guilty. Fine, \$501. (F. D. C. No. 26289. Sample Nos. 27025-K, 27745-K.)

INFORMATION FILED: December 14, 1948, Eastern District of Missouri, against Harry Kaplan, a pharmacist for Fienup's Drug Co., St. Louis, Mo.

INTERSTATE SHIPMENT: Between the approximate dates of January 22 and April 30, 1948, from Philadelphia, Pa., and Detroit, Mich., to St. Louis, Mo., of a number of bottles of *benzedrine sulfate tablets* and *benadryl hydrochloride kapseals*.

LABEL, WHEN SHIPPED: "Benzedrine Sulfate Tablets [or "Kapseals Benadryl Hydrochloride"] * * * Caution: To be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about May 26 and June 2, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be removed from the bottles in which they had been shipped, repacked the drugs into boxes, and sold them without a prescription, which acts by the defendant resulted in the repackaged drugs being misbranded. The repackaged *benzedrine sulfate tablets* were unlabeled. The repackaged *benadryl hydrochloride kapseals* were labeled "Benadryl 50 Mgn."

Misbranding, Section 502 (b) (1), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the repackaged drugs bore no label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the boxes containing the repackaged drugs bore no labeling containing directions for use. Further misbranding, Section 502 (e) (2), the repackaged *benzedrine sulfate tablets* were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and they failed to bear a label showing the common or usual name of the active ingredient.

DISPOSITION: June 13, 1949. A plea of guilty having been entered, the court imposed a fine of \$501.

2795. Misbranding of nephron tablets. U. S. v. 36 Cartons * * *. (F. D. C. No. 26575. Sample No. 49228-K.)

LABEL FILED: June 17, 1949, District of New Mexico.

ALLEGED SHIPMENT: On or about January 12, 1949, by the Neoco Corp., from Los Angeles, Calif.

PRODUCT: 36 cartons, each containing 12 90-tablet bottles, of *nephron* at Albuquerque, N. Mex.

LABEL, IN PART: "Nephron 90 Tablets * * * Each tablet contains: Kidney (desiccated) 7 Grs. With excipients and fillers. Certified color added to coating. Direction: 6 tablets daily or as directed by your doctor, as a source of kidney substance. There are no scientific data available to indicate that the desiccated glandular substance in this product are physiologically or therapeutically active."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the label of the article failed to bear adequate directions for use since it failed to reveal the diseases or conditions of the body for which the article when used as directed would be effective.

DISPOSITION: July 19, 1949. Default decree of condemnation and destruction.

2796. Misbranding of Nue-Ovo. U. S. v. 9 Bottles * * *. (F. D. C. No. 26563. Sample No. 50406-K.)

LABEL FILED: February 25, 1949, Eastern District of Washington.

ALLEGED SHIPMENT: On or about January 25, 1949, by Research Laboratories, Inc., from Portland, Oreg.

PRODUCT: 9 1-pint bottles of *Nue-Ovo* at Walla Walla, Wash.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to reveal the diseases or conditions of the body for which the article when used as directed would be effective.

DISPOSITION: July 19, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2797. Adulteration of chorionic gonadotropin. U. S. v. 491 Vials * * * (and 1 other seizure action). (F. D. C. Nos. 27020, 27021. Sample Nos. 11294-K, 11296-K.)

LABELS FILED: April 21, 1949, Eastern and Southern Districts of New York.

ALLEGED SHIPMENT: On or about December 17 and 24, 1948, by Associated Ross-Good Laboratories, Inc., from Philadelphia, Pa.

PRODUCT: 561 10-cc. vials of *chorionic gonadotropin* at Brooklyn and New York, N. Y. The product was invoiced as "Chorionic Gonadotropin."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since it was for parenteral administration and was not sterile.

DISPOSITION: June 17 and July 5, 1949. Default decrees of condemnation and destruction.

2798. Adulteration and misbranding of adhesive strips. U. S. v. 2,880 Packages
* * *. (F. D. C. No. 27043. Sample No. 41585-K.)

LIBEL FILED: April 13, 1949, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about March 9, 1949, by C. I. Lee & Co., from Carlstadt, N. J.

PRODUCT: 2,880 packages of *adhesive strips* at Detroit, Mich.

LABEL, IN PART: "Sanette 6 Adhesive Strips Sterilized Sanette Mfg. Co., Yonkers, New York."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [Adhesive Absorbent Compress]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading.

DISPOSITION: June 13, 1949. Default decree of condemnation and destruction.

2799. Adulteration and misbranding of adhesive strips. U. S. v. 91 Boxes * * *.
(F. D. C. No. 26987. Sample No. 11188-K.)

LIBEL FILED: On April 8, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about February 17, 1949, by the Sanette Mfg. Co., Inc., from Carlstadt, N. J.

PRODUCT: 91 boxes of *adhesive strips* at New York, N. Y.

LABEL, IN PART: (Box) "Sanette 100 Sterilized Waterproof Adhesive Strips Individually Wrapped."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [Adhesive Absorbent Compress]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, but its quality and purity fell below the official standard since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading.

DISPOSITION: April 29, 1949. Default decree of condemnation and destruction.

2800. Adulteration of prophylactics. U. S. v. 13 Cylinders * * *. (F. D. C. No. 26918. Sample Nos. 1143-K to 1145-K, incl.)

LIBEL FILED: April 5, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 30, 1949, by the Klingfast Rubber Co., from Atlanta, Ga. This was a return shipment.

PRODUCT: 13 fiber cylinders containing 1,909 gross of *prophylactics* at Akron, Ohio. Examination of samples showed that 3 percent were defective in that they contained holes.

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

DISPOSITION: July 15, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2801. Misbranding of Anbesol. U. S. v. 11 Cartons * * *. (F. D. C. No. 27001. Sample No. 56191-K.)

LIBEL FILED: April 19, 1949, Eastern District of New York.

ALLEGED SHIPMENT: On or about March 22, 1949, by the Anbesol Co., from Newark, N. J.

PRODUCT: 11 cartons, each containing 12 packages, and each package containing a circular entitled "You'll never know when you'll need Anbesol" and one 4-fluid dram bottle, of *Anbesol* at Brooklyn, N. Y. Analysis showed that the product consisted essentially of alcohol 70 percent, benzocaine, a cresol, and glycerin, with small proportions of carbolic acid and iodine.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements were false and misleading since the article was not effective in the treatment of the conditions represented and suggested: (Display carton) "Use for Teething Babies * * * sore gums * * * earache, sore throat" and (circular) "Kill infection * * * teething babies * * * toothache * * * Mouth and lip sores * * * earache * * * sore gums * * * will prevent infection."

DISPOSITION: June 17, 1949. Default decree of condemnation and destruction.

2802. Misbranding of Ce Kelp. U. S. v. 33 Jars * * *. (F. D. C. No. 26939. Sample No. 41822-K.)

LIBEL FILED: March 30, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about October 19, 1948, and January 21 and 30, 1949, by the Dental Research Co., from St. Petersburg, Fla.

PRODUCT: 33 1,000-tablet jars of *Ce Kelp* at Chicago, Ill., together with a number of pamphlets entitled "To Your Health" and "Ce Kelp."

LABEL, IN PART: "Ce Kelp A Vegetable Sea Food."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was effective in the treatment and prevention of obesity, thinness, dental decay, pyorrhea, arthritis, glandular malfunction, premature aging, and degenerative changes in the body; that the use of the article would compensate for all mineral deficiencies in the diet and would promote and insure health; and that there are differences of opinion concerning the nutritional value of the small quantities of minerals other than calcium, phosphorus, iron, and iodine, which would be provided by the recommended daily intake of the article. The article would not be effective for the purposes represented, and there are no differences of opinion concerning the nutritional value of the minerals referred to.

DISPOSITION: May 13, 1949. Default decree of condemnation and destruction.

*See also Nos. 2792, 2798, 2799.

2803. Misbranding of Korvo. U. S. v. 266 Bottles, etc. (F. D. C. No. 27011. Sample No. 51279-K.)

LABEL FILED: April 19, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: On or about February 3, 1949, by the Korvo Co., from Chicago, Ill.

PRODUCT: 266 8-ounce bottles of *Korvo* at Cleveland, Ohio, in the possession of Gray Drug Stores, Inc., together with one copy of a circular entitled "Selling Information" and 6 copies of an advertising mat entitled "Are you Worried," which were received by the consignee from the Korvo Co. during November 1948, and March 1949, and one copy of a bulletin which had been prepared by the consignee and a newspaper clipping from the Columbus Citizen newspaper. Copies of the above printed matter were supplied to the retail outlets of Gray Drug Stores, Inc., with the product.

Examination showed that the product consisted essentially of water, alcohol, benzyl alcohol, and a small amount of lactic acid.

LABEL, IN PART: "K Korvo Application For Scalp and Hair."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular, bulletin, advertising mat, and newspaper clipping were false and misleading since the statements represented that the article was effective in the treatment of scalp disorders, including itching scalp, dandruff, baldness, and infection. The article was not effective in the treatment of such conditions. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: June 20, 1949. The Korvo Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

2804. Misbranding of Vola Oil. U. S. v. 11 Bottles, etc. (F. D. C. No. 27192. Sample No. 13465-K.)

LABEL FILED: May 9, 1949, District of Delaware.

ALLEGED SHIPMENT: On or about March 14, 1949, by David H. Blanck & Co., from Philadelphia, Pa.

PRODUCT: 11 3-ounce bottles of *Vola Oil* at Wilmington, Del., together with a number of streamers entitled "Vola Oil." Examination showed that the product consisted essentially of mineral oil, pine tar oil, and perfume.

LABEL, IN PART: (Bottle) "Vola Oil Hair and Scalp Lubricator * * * Vola Laboratories Philadelphia 30, Pa."

NATURE OF CHARGE: Misbranding, Section 502 (a), the pictures on the streamer of a woman before and after using the product, one with thin hair and the other with a thick growth of hair, were false and misleading since the pictures represented and suggested that the article was effective to promote the growth of hair, whereas the article was not effective for such purposes.

DISPOSITION: June 6, 1949. Default decree of condemnation and destruction.

2805. Misbranding of Theraplate (device). U. S. v. 80 Cartons * * *. (F. D. C. No. 26981. Sample No. 41608-K.)

LABEL FILED: April 11, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about February 28, 1949, by Amrum Metal, Inc., from New York, N. Y.

PRODUCT: 80 cartons, each containing a guarantee card entitled "Guarantee Bond," a leaflet entitled "For best results read these Theraplate instructions carefully," and one *Theraplate* (device), at Chicago, Ill. The device consisted of a resistance wire imbedded in a glass plate and mounted on a metal base.

LABEL, IN PART: "Infra Appliance Corp., New York Theraplate."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the device were false and misleading since the device was not an effective treatment for the diseases and conditions stated and implied: (Card) " * * * We guarantee relief from Arthritis, Rheumatism, Sinus conditions, Hay Fever * * *" and (leaflet) "* * * Sufferers from discomforts caused by Arthritis, Sinusitis, Phlebitis, Hay Fever, Rheumatism and other painful conditions, find satisfying relief in Theraplate's health rays * * * For Treatment of Arthritic, Rheumatic and other chronic conditions * * * Three such treatments per day will bring more satisfying, longer-lasting relief from the most agonizing pain * * * For Treatment of Sinusitis, Hay Fever * * * We guarantee relief from Arthritis, Rheumatism, Sinus conditions, Hay Fever * * *."

DISPOSITION: June 1, 1949. Mandel Brothers, Inc., Chicago, Ill., claimant; having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the devices be released under bond for relabeling under the supervision of the Federal Security Agency.

2806. Misbranding of Therm-Massage Infra-Red Heat Applicator. U. S. v. 42 Cartons * * * (and 3 other seizure actions). (F. D. C. Nos. 26954, 26955, 26974, 27159. Sample Nos. 3273-K, 41311-K, 41312-K, 51526-K.)

LIBELS FILED: March 24 and April 19 and 22, 1949, Northern District of Ohio, Western District of Washington, and District of Maryland.

ALLEGED SHIPMENT: Between October 30, 1947, and March 9, 1949, by Sibert & Co., from East Orange and Newark, N. J.

PRODUCT: 186 cartons at Cleveland, Ohio, 1,165 cartons at Seattle, Wash., and 9 cartons at Baltimore, Md. Each carton contained 1 *Therm-Massage Infra-Red Heat Applicator*. There also were quantities of accompanying printed matter, some of which had been shipped with the device and some of which had been shipped separately. The printed matter consisted of circulars, leaflets, and display cards entitled "Therm-Massage Infra-Red Heat Applicator," circulars entitled "Sunday, Dec. 12, 1948" and "Abraham & Strauss Brooklyn Sold Out in Three Hours," a newspaper mat entitled "Heat Massage Those Pains Away," display cards entitled "Relieve Pain Quickly," leaflets entitled "Earn Extra Profits" and "A Few Sales Results From Ads," and leaflets containing various newspaper reprints.

Examination showed that the device consisted of two pieces of molded bakelite, one serving as the handle and the other containing an electrically heated coil.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the device were false and misleading since the device was not effective for the purposes represented. The statements represented and suggested that the device was effective to relieve colds, sinusitis, rheumatic pains, muscular aches and pains, backaches, toothaches, stiff neck, sore throat, pains

in back, headache, nervous headaches in the back of the head, discomfort and congestion, sprains, cramps in the feet or legs, bruises, arthritis, bursitis, neuritis, and neuralgia; that the device would preserve youth and beauty; and that it would aid in preventing the formation of wrinkles.

DISPOSITION: April 29, May 23, and June 15, 1949. Bill Plackas, Seattle, Wash., claimant for the Washington lot, and Sibert & Co., claimant for the other lots, having consented to the entry of decrees, judgments of condemnation were entered. The court ordered that the devices be released under bond for relabeling under the supervision of the Federal Security Agency.

2807. Misbranding of violet ray device. U. S. v. 13 Cases, etc. (F. D. C. No. 26995. Sample Nos. 25833-K, 25834-K.)

LABEL FILED: April 13, 1949, District of Minnesota.

ALLEGED SHIPMENT: On or about November 5 and 27 and December 3, 1948, and January 6, February 13, and March 3, 1949, by Montgomery Ward & Co., from Galewood and Chicago, Ill., and Oakland, Calif., and by Master Appliances, Inc., from Chicago, Ill.

PRODUCT: 13 cases each containing a circular entitled "The Master High Frequency," a device labeled "20W 115V No. M66 The Master Electric Co. Chicago," a general electrode, a comb rake electrode, and a throat electrode; and 26 cases each containing a circular of the same title, a device similarly labeled, and a general electrode.

Examination showed that each of the devices consisted essentially of Geissler's tubes of various shapes, with a transformer assembly to activate them, designed to apply an intermittent ray discharge to the body.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since the devices were not effective in the treatment of the conditions and diseases stated and implied and were not capable of producing the effects claimed. The statements represented and suggested that the devices would be effective in the treatment of faulty circulation and impure blood; that they would be effective in preventing deterioration of the body, failure of the digestive organs to function properly, sluggishness and weakness of the internal organs, and weaknesses peculiar to men and women; that they would give excellent results in local conditions; that they would stimulate the circulation; that they would produce a sedative or quieting effect and would tend to establish a normal equilibrium of the nervous system; that they would be efficacious in relieving painful sensations and in soothing irritated nerves; that they would be efficacious as a stimulant and tonic; that they would be efficacious for facial and body treatment; that they would be efficacious in the treatment of rheumatism, lumbago, and neuritis; that they would be efficacious in the treatment of the scalp, spine, eyes, and ear; that they would be efficacious for stimulating the hair; that they would be efficacious in the treatment of cystitis, strictures, gonorrhea, and prostate and vaginal troubles; and that they would promote circulation and be effective in the treatment of many ailments.

DISPOSITION: August 4, 1949. Master Appliances, Inc., Chicago, Ill., claimant, having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the devices be released under bond for relabeling under the supervision of the Federal Security Agency.

2808. Misbranding of Vitalitone (device). U. S. v. 9 Devices * * *. (F. D. C. No. 26985. Sample Nos. 55139-K, 55140-K.)

LIBEL FILED: April 11, 1949, Western District of Oklahoma.

ALLEGED SHIPMENT: By Professional Aids, Inc., from Salt Lake City, Utah. The devices were shipped on or about February 19 and March 1, 1949, and quantities of printed matter were shipped on or about March 6, 1949.

PRODUCT: 9 *Vitalitone* devices at Oklahoma City, Okla., together with copies of a circular entitled "Placements for Various Conditions," copies of a body chart, and copies of a mailing circular. The device was electrical and was designed for applying the household current to the body following rectification and modulation. The strength of the current could be varied, and the current could be supplied either steadily or intermittently.

LABEL, IN PART: "Vitalitone Model B."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the circulars and body charts were false and misleading. The statements represented and suggested that the device was an adequate and effective treatment for rheumatism, arthritis, charleyhorse, liver disorders, kidney disorders, paralysis, prolapse of colon, prolapse of female organs, angina pectoris, nervous indigestion, high blood pressure, low blood pressure, tense muscles, constipation, asthma, fallen arches, sinusitis, hay fever, nervous tension, and muscular atrophy; and that it would be effective for improving defective vision, rejuvenating the bust, and removing double chin and bags from under the eyes. The device was not an adequate and effective treatment for such diseases and conditions, and it would not fulfill the promises of benefit stated and implied.

DISPOSITION: July 13, 1949. Professional Aids, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the devices be released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

2809. Misbranding of Bucokol, Arsulin Powder, thionitrate tablets, and guaiacol. U. S. v. 123 Bottles, etc. (F. D. C. No. 26962. Sample Nos. 34123-K to 34126-K, incl.)

LIBEL FILED: April 1, 1949, Northern District of California.

ALLEGED SHIPMENT: On or about November 29, 1946, and May 2 and 9 and July 8 and 19, 1947, by Vet Products, Inc., from Kansas City, Mo.

PRODUCT: 123 1-pint bottles of *Bucokol*, 70 1-pound cartons of *Arsulin Powder*, 30 100-tablet bottles of *thionitrate tablets*, and 5 bottles of *guaiacol* at Oakland, Calif. Analyses disclosed that the *Bucokol* consisted essentially of mineral oil, approximately 75 percent, soap, phenolic compounds including *guaiacol*, eucalyptus oil, camphor, and a small proportion of water; that the *Arsulin Powder* consisted essentially of a bark, linseed meal, arsenic trioxide, and sulfur; that the *thionitrate tablets* consisted essentially of sodium nitrate, sodium thiosulfate, dextrose, and ultramarine blue; and that the *guaiacol* consisted essentially of 69 percent mineral oil, soap, phenolic compounds including *guaiacol*, eucalyptus oil, camphor, and a small proportion of water.

NATURE OF CHARGE: *Bucokol*. Misbranding, Section 502 (a), the label statement "An Aid in Treating Simple Colds of Livestock and Poultry" was false and misleading since the article was not effective as an aid in treating simple colds of livestock and poultry.

Arsulin Powder. Misbranding, Section 502 (a), the label statement "An Aid in the Treating of Suppurative Disorders of Large Animals, Particularly Horses" was false and misleading since the article was not effective as an aid in the treatment of suppurative disorders of large animals, particularly horses.

Thionitrate tablets. Misbranding, Section 502 (a), the label statements "Antidote for various poisonings in livestock; prussic acid, toxic plants, molds, fungi, lead, arsenic, thallium, etc.; check diarrhea in calves" were false and misleading since the article was not effective as an antidote for the poisonings stated, and it was not effective to check diarrhea in calves.

Guaiacol. Misbranding, Section 502 (a), the label statement "Orally for respiratory afflictions; colics; bloat and digestive fermentations; lymphangitis and congestions" was false and misleading since the article was not effective in the treatment of the disease conditions stated and implied.

DISPOSITION: May 3, 1949. Default decree of condemnation and destruction.

2810. Misbranding of Speedway Cough and Distemper Remedy, Speedway Condition Powder, Speedway Hoof Tonic, Black Perfection Salve, and Speedway Absorbent Liniment. U. S. v. 7 Bottles, etc. (F. D. C. No. 26662. Sample Nos. 30648-K to 30652-K, incl.)

LABEL FILED: March 17, 1949, Southern District of California.

ALLEGED SHIPMENT: On or about May and September 1948, by the Energy Drug Co., from Cleveland, Ohio.

PRODUCT: 7 1-pint bottles of *Speedway Cough and Distemper Remedy*; 10 9-ounce boxes of *Speedway Condition Powder*; 2 1-quart cans of *Speedway Hoof Tonic*; 14 3-ounce jars of *Black Perfection Salve*; and 9 1-gallon cans and 9 1-quart cans and 11 12-ounce bottles of *Speedway Absorbent Liniment*, at Beverly Hills, Calif., together with a number of circulars entitled "Speedway Veterinary Remedies." Analyses disclosed that the *Speedway Cough and Distemper Remedy* consisted essentially of water, sugar, ammonium chloride, ammonium carbonate, and small proportions of alkaloids including strychnine; that the *Speedway Absorbent Liniment* consisted essentially of alcohol, benzoin, and other aromatic compounds; that the *Speedway Condition Powder* consisted essentially of iron sulfate, fenugreek, and small proportions of santonin and nux vomica; that the *Speedway Hoof Tonic* consisted essentially of petroleum oil; and that the *Black Perfection Salve* consisted essentially of sulfur, charcoal, tannic acid, camphor, and a lead compound in an ointment base of lard.

NATURE OF CHARGE: *Speedway Cough and Distemper Remedy.* Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. These statements represented and suggested that the article was an effective treatment of cough, distemper, shipping fever, colds, epizootic, lung fever, pneumonia, and kidney diseases of horses, and that it would relieve fever and create an appetite. The article was not an effective treatment for such diseases and conditions. Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, one of which was nux vomica, a strychnine bearing drug, and its label failed to bear a statement of the quantity or proportion of strychnine contained in the article.

Speedway Absorbent Liniment. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. These statements represented and suggested that the article was an effective treatment for bad legs, all lameness, bowed tendons, big knees, bad ankles, weak

joints, and bad back in horses, and that it would restore natural respiration and put the hair in better condition. The article was not an effective treatment for such conditions. Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

Speedway Condition Powder. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. These statements represented and suggested that the article was a wonderful, superior tonic, tissue builder, blood purifier, conditioner, and a general body builder; that it would keep horses healthy and strong; and that it would remove worms from horses. The article was not an effective treatment for such conditions. Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of the particular iron compound used and the quantity or proportion of strychnine contained in the article.

Speedway Hoof Tonic. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. These statements represented and suggested that the article was an adequate treatment for bad feet of horses, contracted feet, thrush, etc., and that it was a hoof tonic which would grow a new hoof and keep the feet in perfect condition. The article was not an adequate treatment for such conditions; it would not fulfill the promises of benefit made for it; and its labeling also was false and misleading since it contained false and misleading representations with respect to the *Speedway Absorbent Liniment*, *Speedway Condition Powder*, and *Speedway Cough and Distemper Remedy*. Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

Black Perfection Salve. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. These statements represented and suggested that the article had healing properties for chafes, cracked heels, saddle galls, and all wounds and sores on horses or cattle, and that it would actually grow a soft, pliable, yet tough skin, keep horses free from pain and discomfort, and grow hair of a natural color. The article was not capable of fulfilling such promises of benefit made for it.

DISPOSITION: May 13, 1949. Default decree of condemnation and destruction.

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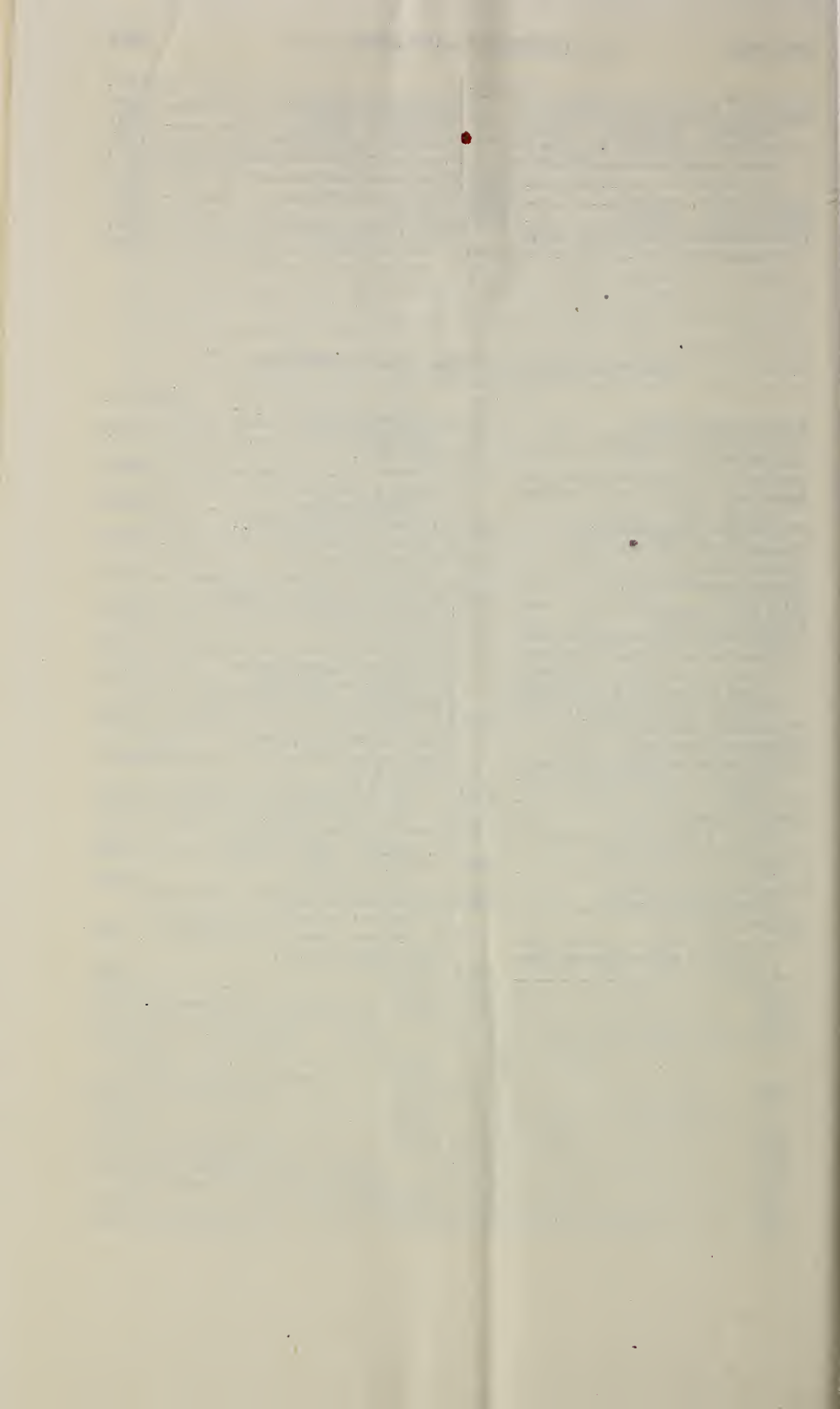
PRODUCTS

	N. J. No.		N. J. No.
Anbesol	2801	Gonadotropin, chorionic.....	2797
Arsulin Powder.....	2809	Guaiacol	2809
Bandages and dressings.....	2798, 2799	Hair and scalp preparations.....	2803, 2804
Benadryl hydrochloride capsules.....	2794	Injection preparations. <i>See</i> Parenteral drugs.	
Benzedrine sulfate tablets.....	2794	Korvo	2803
Black Perfection Salve.....	2810	Magnolia Blossom Vaginal Suppositories	2792
Bucokol.....	2809	Nephron tablets.....	2795
Ce Kelp.....	2802	Nue-Ovo	2796
Chorionic gonadotropin.....	2797	Parenteral drugs.....	2797
Cosmetics (subject to the drug provisions of the Act).....	2803, 2804	Prophylactics.....	2800
Devices	2800, 2805-2808	Salve, Black Perfection.....	2810
Gattis' Worm Oil.....	2793		

	N. J. No.		N. J. No.
Speedway Cough and Distemper Remedy, Speedway Condition Powder, Speedway Hoof Tonic, and Speedway Absorbent Liniment	2810	Thionitrate tablets	2809
Suppositories, vaginal	2792	Urethane, syrup	2791
Thermaplate (device)	2805	Vaginal suppositories	2792
Therm-Massage Infra-Red Heat Applicator	2806	Veterinary preparations	2809, 2810
		Violet ray device	2807
		Vitalitone (device)	2808
		Vola Oil	2804
		Worm Oil, Gattis'	2793
		Worm remedy	2793

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N. J. No.		N. J. No.
Amrum Metal, Inc.:		Klingfast Rubber Co.:	
Thermaplate (device)	2805	prophylactics	2800
Anbesol Co.:		Korvo Co.:	
Anbesol	2801	Korvo	2803
Associated Ross-Good Laboratories, Inc.:		Lee, C. I., & Co.:	
chorionic gonadotropin	2797	adhesive strips	2798
Blanck, David H., & Co.:		Master Appliances, Inc.:	
Vola Oil	2804	violet ray device	2807
Dental Research Co.:		Master Electric Co.:	
Ce Kelp	2802	violet ray device	2807
Energy Drug Co.:		Montgomery Ward & Co.:	
Speedway Cough and Distemper Remedy, Speedway Condition Powder, Speedway Hoof Tonic, Black Perfection Salve, and Speedway Absorbent Liniment	2810	violet ray device	2807
Fienup's Drug Co.:		Neoco Corp.:	
benzedrine sulfate tablets and benadryl hydrochloride capsules	2794	nephron tablets	2795
Gattis Chemical Co.:		Professional Aids, Inc.:	
Gattis' Worm Oil	2793	Vitalitone (device)	2808
Gray Drug Stores, Inc.:		Research Laboratories, Inc.:	
Korvo	2803	Nue-Ovo	2796
Infra Appliance Corp.:		Sanette Mfg. Co., Inc.:	
Thermaplate (device)	2805	adhesive strips	2798, 2799
Kaplan, Harry:		Sibert & Co.:	
benzedrine sulfate tablets and benadryl hydrochloride capsules	2794	Therm-Massage Infra-Red Heat Applicator	2806
		South Bend Remedy Co.:	
		vaginal suppositories	2792
		Thompson, Marvin R., Inc.:	
		syrup urethane	2791
		Vet Products, Inc.:	
		Bucokol, Arsulin Powder, thionitrate tablets, and guaiacol	2809
		Vola Laboratories:	
		Vola Oil	2804



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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2811-2830

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., February 6, 1950.

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 2822, 2825, 2829; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2822, 2825, 2829; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2822, cosmetic, actionable under the drug provisions of the Act, No. 2828.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2811. Adulteration of Geo-Mineral. U. S. v. 224 Bottles * * *. (F. D. C. No. 27174. Sample No. 46051-K.)

LIBEL FILED: On or about May 9, 1949, Western District of Missouri.

ALLEGED SHIPMENT: On or about March 19, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo., to Springfield, Mo. A 10-barrel lot of material had been shipped by W. L. Newcomb, from Bay Springs, Miss., to Vi-Jon Laboratories, Inc., on or about February 28 and March 15, 1949. The Springfield shipment consisted of a portion of such material which had been diluted with tap water and which was bottled and labeled by Vi-Jon Laboratories, Inc.

PRODUCT: 224 3-ounce bottles of *Geo-Mineral* at Springfield, Mo.

LABEL, IN PART: "Geo-Mineral * * * Sole Distributor Geo-Mineral Company St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

DISPOSITION: June 1949. Default decree of condemnation and destruction.

2812. Adulteration and misbranding of Geo-Mineral. U. S. v. 663 Bottles * * *. (F. D. C. No. 27194. Sample No. 50438-K.)

LIBEL FILED: May 11, 1949, District of Idaho.

ALLEGED SHIPMENT: On or about March 7, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

PRODUCT: 663 3-ounce bottles of *Geo-Mineral* at Boise, Idaho, in possession of Pay Less Drug Stores, Inc., together with four copies of a newspaper advertisement entitled "Easter Value Parade." Examination showed that the product was an amber liquid contaminated with mold.

LABEL, IN PART: "Geo-Mineral * * * Sole Distributor Geo-Mineral Company St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

Misbranding, Section 502 (a), certain statements in the above-mentioned newspaper advertisement were false and misleading since the article was not effective for the purposes represented. The statements represented and suggested that the article was effective in the treatment of stomach ailments, weak kidneys, rheumatic pains, arthritis, neuritis, headaches, nervousness, acid toxins, bloating, lack of vitality and energy, poor appetite, underweight, dizzy spells, rheumatism, kidney ailments, and the condition in which one feels old before his time and life appears not worth living; that the article would give strength, pep, life, and energy; and that it would give the eyes a bright spark, and the mind, brilliance. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: June 12, 1949. Default decree of forfeiture and destruction.

2813. Adulteration of Acid Iron Earth Water. U. S. v. 1 Barrel * * * (and 1 other seizure action). (F. D. C. Nos. 27242, 27265. Sample Nos. 1728-K, 53472-K.)

LIBELS FILED: On or about May 16 and 26, 1949, Northern District of Georgia and Northern District of Alabama.

ALLEGED SHIPMENT: On or about April 8 and May 10, 1949, by W. L. Newcomb, from Bay Springs, Miss.

PRODUCT: 1 15-gallon barrel and 2 50-gallon barrels of *Acid Iron Earth Water*, at Atlanta, Ga., and Hamilton, Ala.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

DISPOSITION: June 16 and 28, 1949. Default decrees of condemnation and destruction.

2814. Adulteration of a mineral solution. U. S. v. 1 Barrel * * *. (F. D. C. No. 27333. Sample No. 63614-K.)

LIBEL FILED: June 22, 1949, Southern District of Florida.

ALLEGED SHIPMENT: On or about August 19, 1948, from Bay Springs, Miss.

PRODUCT: 1 30-gallon barrel of a *mineral solution* at Sarasota, Fla. Examination showed that the product was a water solution of ferric sulfate and that it was contaminated with mold.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: August 8, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2815. Adulteration of distilled water. U. S. v. 300 Ampuls * * *. (F. D. C. No. 27313. Sample No. 56203-K.)

LIBEL FILED: June 13, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about May 3, 1949, by Harvey Laboratories, Inc., from Philadelphia, Pa.

PRODUCT: 300 10-cc. ampuls of *distilled water* at New York. N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since the article was contaminated with undissolved material.

DISPOSITION: July 5, 1949. Default decree of condemnation and destruction.

2816. Adulteration of procaine hydrochloride. U. S. v. 65 Vials * * *. (F. D. C. No. 27296. Sample No. 8537-K.)

LIBEL FILED: June 1, 1949, District of New Jersey; amended libel filed June 8, 1949.

ALLEGED SHIPMENT: On or about April 4, 1949, by the C. F. Kirk Co., from New York, N. Y.

PRODUCT: 65 30-cc. vials of *procaine hydrochloride* at Newark, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Procaine Hydrochloride Ampuls," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: July 25, 1949. Default decree of condemnation and destruction.

2817. Adulteration and misbranding of Thiocyl. U. S. v. 17 Boxes, etc. (F. D. C. No. 27195. Sample Nos. 11277-K, 11287-K.)

LIBEL FILED: May 9, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about January 21, 1949, by Torigian Laboratories, Inc., from Queens Village, N. Y.

PRODUCT: 17 12-ampul boxes, 4 25-ampul boxes, 3 100-ampul boxes, and 45 3-ampul boxes of *Thiocyl* at Montclair, N. J. Analysis showed that the product consisted of a solution containing not more than 7.3 percent of sodium thiosalicylate.

LABEL, IN PART: "Ampul 2 cc. Size Thiocyl Sod. Thiosalicylate 10%."

NATURE OF CHARGE: Adulteration, Section 501 (c) the strength of the article differed from that which it purported to possess, namely, sodium thiosalicylate 10 percent.

Misbranding, Section 502 (a), the label statement "Sod. Thiosalicylate 10%" was false and misleading.

DISPOSITION: July 11, 1949. Default decree of condemnation. The court ordered that a portion of the product be delivered to the Food and Drug Administration, and the remainder be destroyed.

2818. Adulteration and misbranding of adhesive bandages. U. S. v. 74 Cartons * * *. (F. D. C. No. 27295. Sample No. 62214-K.)

LIBEL FILED: June 2, 1949, District of Massachusetts.

ALLEGED SHIPMENT: On or about April 26, 1949, by the Hampton Mfg. Co., from Carlstadt, N. J.

PRODUCT: 74 cartons, each containing 36 packages, of *adhesive bandages* at Boston, Mass.

LABEL, IN PART: (Package) "Blue Cross Sterilized 6 Adhesive Bandages."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since the article was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading.

DISPOSITION: July 12, 1949. Default decree of condemnation and destruction.

2819. Adulteration of wound dressing. U. S. v. 128 Bottles * * *. (F. D. C. No. 27193. Sample Nos. 9467-K, 9486-K.)

LIBEL FILED: May 11, 1949, Southern District of New York.

ALLEGED SHIPMENT: The article, after its manufacture in Mount Vernon, N. Y., was transported to Jersey City, N. J., by Gershon Shugar, secretary-treasurer of Rona Laboratories, Inc., on or about October 1, 1948, where it was subjected to a sterilization process and then returned to Mount Vernon, N. Y. On or about October 18, 1948, it was shipped by Rona Laboratories, Inc., from Mount Vernon, N. Y., to New York, N. Y.

PRODUCT: 128 bottles of *wound dressing* at New York, N. Y. Examination showed that the product was not-sterile but was contaminated with living micro-organisms.

LABEL, IN PART: "Clinico's Sterilized Wound Dressing Yellow Petrolatum U. S. P. Gauze 2 in. x 10 Yds."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since a dressing for wounds should be, and is expected to be, sterile.

DISPOSITION: July 5, 1949. Default decree of condemnation and destruction.

2820. Adulteration and misbranding of prophylactics. U. S. v. 38 Gross * * *. (F. D. C. No. 27351. Sample No. 63615-K.)

LIBEL FILED: July 1, 1949, Southern District of Florida.

ALLEGED SHIPMENT: On or about February 9, 1949, by the Killashun Sales Div., Inc., from Akron, Ohio.

PRODUCT: 38 gross of *prophylactics* at Tampa, Fla. Examination of samples showed that 6.2 percent were defective in that they contained holes.

LABEL, IN PART: "Silver Tex Prophylactic Mfd. By The Killian Mfg. Co., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "For Your Protection" were false and misleading as applied to an article containing holes.

DISPOSITION: July 30, 1949. Default decree of condemnation and destruction.

2821. Supplement to notices of judgment on drugs, No. 2276. U. S. v. 43½ Gross and 112½ Gross of Prophylactics. (F. D. C. No. 16888. Sample Nos. 18372-H, 18373-H.)

On July 21, 1945, a libel was filed against the above-described quantities of *prophylactics*, charging that they were adulterated and misbranded by reason of the fact that they contained holes. On April 22, 1946, judgment of condemnation was entered and the court ordered that the product be released to the claimant under bond, for segregation of the good portion of the product from the bad.

An appeal was taken by the claimant, and on March 4, 1947, the judgment was affirmed. Thereafter, the claimant failed to avail itself of the opportunity to secure release of the product under bond, and on September 12, 1949, judgment of default was entered and the court ordered that the product be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2822. Misbranding of estrogenic substance. U. S. v. 197 Vials * * *. (F. D. C. No. 27331. Sample No. 48470-K.)

LABEL FILED: June 16, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 28, 1949, by the Sonoral Laboratories, from New York, N. Y.

PRODUCT: 197 unlabeled vials of *estrogenic substance* at Sellersville, Pa. The product was packaged in cartons of 24 vials each. No agreement as to labeling existed between the shipper and the dealer.

LABEL, IN PART: (Carton) "10 cc Size * * * Vial Estrone 10% Diol-Sex Suspension Estradiol 20,000 I. U. per cc."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Estradiol 20,000 I. U. per cc." appearing on the cartons was false and misleading, since there is no International Unit of estradiol activity and the statement created the misleading impression that there is some recognized relationship between the potencies of alpha-estradiol and estrone, an estrogen for which there is an International Unit, when in fact there is not; Section 502 (b) (1), the article failed to bear a label on the vials containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), it failed to bear a label on the vials containing an accurate statement of the quantity of the contents; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and the vials containing the article failed to bear a label containing the common or usual name of each active ingredient.

DISPOSITION: July 27, 1949. Default decree of condemnation and destruction.

2823. Misbranding of Sercaps. U. S. v. 97 Bottles, etc. (F. D. C. No. 27216. Sample No. 42350-K.)

LABEL FILED: June 10, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: During November 1948, by Sercaps, Inc., from Detroit, Mich.

PRODUCT: 40 50-tablet bottles, 57 20-tablet bottles, and 79 packets of 8 tablets each, of *Sercaps* at Chicago, Ill., together with a number of leaflets entitled "Sercaps" and display cards entitled "Relief For Piles." Examination showed that the product consisted essentially of coated tablets containing sulfur, potassium tartrate, and plant material.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since the article was not effective in the treatment of the conditions suggested or implied. The statements represented and suggested that the article would be efficacious for the relief of piles; that it would be efficacious in the treatment of the discomfort due to blind, bleeding, and itching hemorrhoids, both internal and external; and that it would ease the pain of piles, allay pile nervousness, and tend to relieve sore and swollen tissue.

DISPOSITION: July 27, 1949. Default decree of condemnation and destruction.

*See also Nos. 2812, 2817, 2818, 2820, 2821.

2824. Misbranding of Abbe Hamon Formula Nos. 2, 4, 6, 8, 11, 12, 13, 14, 15, and 16, Abbe Hamon Tea No. 18, and Abbe Hamon Pommade Cure No. 3. U. S. v. 4 Cans, etc. (F. D. C. No. 27229. Sample Nos. 5842-K, 5844-K, 5846-K, 5848-K, 5851-K to 5856-K, incl., 5858-K, 5862-K.)

LABEL FILED: On or about May 25, 1949, District of Rhode Island.

ALLEGED SHIPMENT: Between the approximate dates of August 19, 1947, and March 9, 1949, by the Botanical & Marine Laboratories, from Manchester, N. H.

PRODUCT: 40 cans of *Abbe Hamon Formulae*, 4 cans of *Abbe Hamon Tea No. 18*, and 2 tubes of *Abbe Hamon Pommade* at Central Falls, R. I., together with a number of leaflets entitled "Abbe Hamon's 20 Herb Teas." An additional leaflet entitled "This herb Formula is one of the Twenty" was enclosed in each can of the *Formula No. 11* and *Tea No. 18*. Analyses showed that the *Tea No. 18* consisted essentially of shepherd's-purse leaves, inula root, peppermint leaves, and hazel leaves, and that each of the other products possessed essentially the composition stated on the label.

LABEL, IN PART: "Abbe Hamon Formula * * * ["No. 2 Ingredients: Bark; Oak. Leaves: Bilberry, Horsetail, Woodruff, Roots; Woodruff, Angelica. Vehicle; Hazel leaves," "No. 4 Ingredients: Bark; Oak. Leaves; Catmint, Centaury, Walnut; Roots; Gentian, Calamus. Vehicle: Hazel leaves." "No. 6 Ingredients: Lime, Elder and Feverfew Flowers; Poppy Petals; Oak and Mistletoe Leaves; Nenuphar and Valerian Roots; Hazel Leaves as a vehicle," "No. 8 Ingredients: Bark; Frangula. Leaves; Artemisia, Wormwood, White Horehound. Seeds; Parsley. Vehicle; Hazel leaves," "No. 11 Ingredients: Leaves; Box. Roots; Couchgrass, Patience dock, Liquorice. Seaweed; Fucus Vesiculosus. Vehicle; Hazel leaves," "No. 12 Ingredients: Bark; Frangula. Flower; Scabiosa. Leaves; Chicory, Box, Centaury, St. Johns Wort. Roots; Fumitory, Couch Grass; Gentian. Vehicle; Hazel leaves," "No. 13 Ingredients: Flowers; Lavender. Leaves: Origan. Marjoram. Seeds: Angelica, Anis, Caraway, Coriander, Fennel. Roots; Angelica. Vehicle; Hazel leaves," "No. 14 Ingredients: Bark; Oak. Leaves; Woodruff, Shepherd's-purse. Roots; Bistort Liquorice. Vehicle; Hazel leaves," "No. 15 Ingredients: Flowers; Bugloss. Leaves; White Horehound, Oak Pulmonaria, Borage, Hedge Mustard, Eucalyptus. Roots; Inula, Comfrey. Vehicle; Hazel leaves," and "No. 16 Ingredients: Flowers; Genista, Leaves; Woodruff, Centaury, Gratiola. Roots; Burdock, Thistle Rolland, Liquorice. Seeds; Carrot. Vehicle; Hazel Leaves"]" or "Abbe Hamon Tea No. 18" or "Abbe Hamon * * * Cure No. 3—Pommade."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading since the articles were not effective in the treatment of the conditions or for the purposes stated and implied. The statements represented and suggested that the *Formula No. 2* would be effective as a mild diuretic, purgative, and stimulant, and as an adjunct in the treatment of Albuminuria, Bright's disease, and derivatives; that *Formula No. 4* would be effective in the treatment of anemia and puberty and would be beneficial for pale people; that *Formula No. 6* would be effective in the treatment of neurasthenia, epilepsy, nervous disease, and St. Vitus's dance; that *Formula No. 8* would be effective as a stimulant, astringent, diuretic, and tonic, and as an adjunct in the treatment of menstrual irregularity, insufficiency, menopause, puberty, painful periods, and change of life; that the *Formula No. 11* would be effective in the treatment of obesity, paralysis, high blood pressure, and arteriosclerosis; that *Formula No. 12* would be effective in the treatment of skin troubles, pimples, acne, and rashes; that *Formula*

No. 13 would be effective in the treatment of stomach complaints, with the exception of ulcers; that *Formula No. 14* would be effective as an astringent and emollient and as an adjunct in the treatment of bad circulation, varicose veins, piles, congestion, phlebitis, and hemorrhage; that *Formula No. 15* would be effective as a tonic, emollient, diuretic, and astringent, and as an adjunct in the treatment of coughs, bronchitis, asthma, catarrh, grippe, emphysema, and tuberculosis; that *Formula No. 16* would be effective in the treatment of heart, kidney, liver, and urinary troubles; that the *Tea No. 18* would be effective in the treatment of ulcers of the stomach and the intestines, morning sickness, sea sickness, and ulcerated stomach and intestines; and that the *Pom-made* would be effective in the treatment of "rhumatismes," "douleurs arthritiques," "goutte," and "sciatique."

The above articles were misbranded when introduced into, and while in, interstate commerce, and while held for sale after shipment in interstate commerce.

DISPOSITION: June 27, 1949. Default decree of condemnation and destruction.

2825. Supplement to notices of judgment on drugs, No. 1326. U. S. v. Elmer J. Dailey (Dailey's Laboratories). (F. D. C. No. 11424. Sample Nos. 57639-F, 57640-F.)

On September 15, 1944, following a verdict of guilty on charges based upon the interstate shipment of misbranded drugs known as *Sugretus* and *Sunol*, the court imposed a fine of \$250 and placed the defendant on probation for 5 years.

On February 10, 1948, a hearing was held to revoke the probation of Mr. Dailey; and at the conclusion of all testimony, the court found that the defendant was guilty of misbranding *Sugretus* while on probation, in the same manner as was charged in the original proceedings. The court thereupon revoked Mr. Dailey's probation and imposed a fine of \$750 and costs.

2826. Misbranding of Neg-A-Pos heel plates. U. S. v. 84 Devices, etc. (F. D. C. No. 27267. Sample No. 8536-K.)

LABEL FILED: May 25, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about January 1949, from Manchester Center, Vt.

PRODUCT: 84 devices known as *Neg-A-Pos* at Hackensack, N. J., in the possession of Mr. G. V. Crowell, together with a number of leaflets entitled "*Neg-A-Pos*" which Mr. Crowell had printed locally. The device consisted of a copper and zinc plate, each pasted to a piece of flannel.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the accompanying leaflets were false and misleading since the device was not effective in the treatment of the conditions stated and implied nor for the purposes mentioned: "*Neg-A-Pos* relieves Arthritis & Sacrailliac Back, stiffness and pain due to Rheumatism and muscular pains * * * It Stimulates the Natural electrical impulses of the System and helps Nature in a natural way to Exude or carry off accumulated deposits which cause pain and stiffness. You will note a Comfortable Warming of the Feet within a few hours which is a Natural Action. * * * In the Heel they come in Contact with the Large Nerve and Blood Vessels of the Leg. That is where they start to work." The devices were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 11, 1949. Default decree of condemnation. One dozen of the devices were ordered delivered to the Food and Drug Administration, for experimental and exhibition purposes, and the remaining devices were ordered destroyed.

2827. Misbranding of Vibro-Sazh devices. U. S. v. 10 Cartons * * *.
(F. D. C. No. 27264. Sample No. 19350-K.)

LABEL FILED: May 23, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: On or about April 27, 1949, by Vibrosazh, Inc., from Faribault, Minn.

PRODUCT: 10 cartons each containing a device known as *Vibro-Sazh* and a circular entitled "Glowing Health with Vibro-Sazh" at Cleveland, Ohio. This product was essentially a vibrating and massaging device. It consisted of a cup-shaped device to be attached to the hose of a vacuum cleaner, so that the flow of air would cause a vibration.

LABEL, IN PART: (Circular) "Glowing Health With Vibro-Sazh * * * Vibro-Sazh Health Vibrator introduces New Air Method Of Vibration and Massage."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular were false and misleading since the device would not fulfill the promises of benefit stated and implied. The statements represented and suggested that the device would enable one to have glowing health; that it would be efficacious in the cure, mitigation, and treatment of the discomforts of lumbago, sinus, rheumatism, arthritis, and muscular aches and pains due to poor circulation; that it would take off unwanted and unsightly pounds and replace them with healthy firm tissue; that it would stimulate the circulation in the deeper tissue and aid in the removal and discharge of waste products, such as fatigue acids and tissue debris; that it would promote increased circulatory action; that it would melt away excessive fatty tissue, induce sleep, and aid in the removal of wrinkles, crow's feet, and double chin; that it would stimulate growth of firm tissue where added fullness was desired; that it would help to bring about a better supply of fresh blood; that it would comfort and sooth jittery, strained, and overworked nerves and muscles; that it would relieve ordinary headaches, dull sinus pains above the eyes, and head and chest colds; that it would help to promote sound sleep and would be of great help in the treatment of many disabilities; that it would be of real value in most types of convalescence; that it would be a big factor in restoring one's body to youthful freshness; and that it would be efficacious in the cure, mitigation, and treatment of nervousness, backaches, insomnia, and aches and pains in the back, arm, and shoulder muscles.

DISPOSITION: July 15, 1949. Default decree of condemnation and destruction.

2828. Misbranding of Happy Jack Sarcoptic Mange Medicine. U. S. v. 23 Cartons, etc. (F. D. C. No. 27186. Sample No. 3276-K.)

LABEL FILED: May 5, 1949, District of Maryland.

ALLEGED SHIPMENT: On or about April 8, 1949, by Happy Jack, Inc., from Farmville, N. C.

PRODUCT: *Happy Jack Sarcoptic Mange Medicine*. 23 cartons, each containing 1 10-ounce bottle, and 10 cartons, each containing 1 24-ounce bottle, at Baltimore, Md. Analysis showed that the product contained carbolic acid (0.6%), pine tar oil, turpentine oil, sulfur, and clay in a mixture of vegetable oil and fish oil.

LABEL, IN PART: "Happy Jack Sarcoptic Mange Medicine."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles and in a circular enclosed with the article were false and misleading. These statements represented and suggested that the article when used as directed was safe and effective in the treatment of diseases of the skin of dogs and other animals, whereas the article when applied to the entire surface of the dog was not safe, and when used as directed it was not effective in the treatment of diseases of the skin of dogs and other animals.

Further misbranding, Section 502 (a), certain statements in the circulars were false and misleading. These statements represented and suggested that the article would be effective for use by humans in the treatment of dandruff, eczema, and falling hair, and that it would be effective in promoting a healthier scalp and hair texture, whereas the article would not be effective for such purposes.

DISPOSITION: June 7, 1949. Default decree of condemnation and destruction.

DRUGS FOR VETERINARY USE*

2829. Misbranding of *Dr. Gibbons' Tendene* and *Dr. Gibbons' Wonder Red*. U. S. v. 4 Bottles, etc. (F. D. C. No. 27215. Sample Nos. 31925-K to 31927-K, incl.)

LIBEL FILED: May 17, 1949, Southern District of California.

ALLEGED SHIPMENT: Between the approximate dates of August 30, 1948, and January 11, 1949, by Dr. P. H. Gibbons, from Omaha, Nebr.

PRODUCT: 4 1-pint bottles of *Dr. Gibbons' Tendene* and 87 1-pint bottles of *Dr. Gibbons' Wonder Red* at Los Angeles, Calif. Analyses disclosed that *Dr. Gibbons' Tendene* consisted essentially of cedar oil, camphor oil, turpentine oil, iodine, potassium iodide, alcohol approximately 13 percent, and chloroform approximately 29 percent, and that *Dr. Gibbons' Wonder Red* consisted essentially of azosulfamide, starch, and water.

NATURE OF CHARGE: *Dr. Gibbons' Tendene*. Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article was not effective in the prevention or treatment of the disease conditions of horses stated and implied: (Bottle label) "A Practical Treatment for * * * Glandular Swelling" and (circular attached with a rubber band to some of the bottles) "A Convenient, Modern Way to Treat Lameness Without Bandages * * * stands alone as a treatment for stifle trouble. It is used on all swellings of the horse regardless of cause. * * * For Suspensory Ligament Trouble: * * * For Shoulder Lameness: * * * For Ankle Lameness, Swelling and Osslets: * * * For Sore Throat or any Swelling on Body: * * * Bursitis." Further misbranding, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of the active ingredients contained therein since "oleum cedralae" and "oil terbinth" are not the common or usual names of cedar oil and turpentine oil; and its label failed also to bear the quantity, kind, and proportion of alcohol, and the name and quantity or proportion of chloroform, contained in the article.

Dr. Gibbons' Wonder Red. Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since the article when used as directed was not effective in the treatment of the disease condi-

*See also No. 2828.

tions of horses stated and implied: (Bottle label) "Shipping Fever, Pulmonary Congestion, Distemper, or so-called Stockyards Pneumonia. For any pus condition or discharge from the nostrils or any pus swelling. Blood poisoning, bad or spasmodic cough, kidney troubles, such as horse tying or cording. WONDER RED is used for sore throat, swollen glands, or any lumps or swellings of the legs or body * * * where there is a high temperature * * * until temperature drops to * * * normal * * * For Loss of Appetite * * * For Blood Poison and where temperature is up * * * If legs are swollen use Dr. Gibbons' Tendene twice daily, and apply to any other swelling." Further misbranding, Section 502 (b) (2), the label of the article failed to bear any statement of the quantity of the contents; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

DISPOSITION: June 20, 1949. Default decree of condemnation and destruction.

2830. Misbranding of York's Calf Scour Capsules. U. S. v. 48 Boxes * * *.
(F. D. C. No. 27185. Sample No. 25693-K.)

LIBEL FILED: May 5, 1949, Southern District of Iowa.

ALLEGED SHIPMENT: On or about April 7, 1949, by the Gelatin Products Div., R. P. Scherer Corp., from Detroit, Mich.

PRODUCT: 48 100-capsule boxes of *York's Calf Scour Capsules* at Madrid, Iowa.

LABEL, IN PART: "York's Calf Scour Capsules Each Capsule Contains Vitamin A (from fish liver oil) 5,000 USP Units Nicotinic Acid 50 Milligrams Vitamin D (irradiated ergosterol) 500 USP Units."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements, "Calf Scour Capsules * * * Helpful in preventing common, non-infectious scours, pneumonia, colds * * * If calf is scouring, two capsules a day are recommended," were false and misleading since the article when taken as directed would not be helpful in preventing so-called noninfectious scours, pneumonia, and colds of calves, and was not effective in the treatment of calves which are scouring.

DISPOSITION: June 27, 1949. Default decree of condemnation and destruction.

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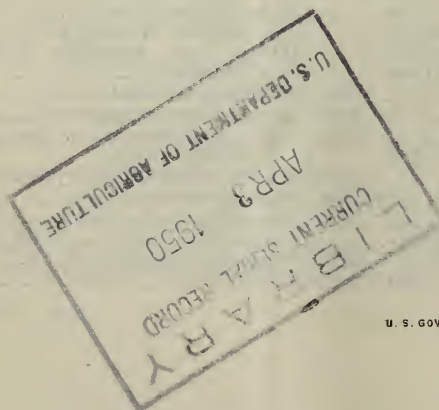
PRODUCTS

	N. J. No.		N. J. No.
Abbe Hamon Formula Nos. 2, 4, 6, 8, 11, 12, 13, 14, 15, and 16,		Gibbons', Dr., Tendene, and Dr.	
Abbe Hamon Tea No. 18, and		Gibbons' Wonder Red-----	2829
Abbe Hamon Pommade Cure		Happy Jack Sarcoptic Mange	
No. 3-----	2824	Medicine-----	2828
Acid Iron Earth Water-----	2813	Heel plates, Neg-A-Pos-----	2826
Bandages, adhesive-----	2818	Hemorrhoids, remedy for-----	2823
Cosmetic (subject to the drug		Injection preparations. See Pa-	
provisions of the Act)-----	2828	renteral drugs.	
Devices-----	2820, 2821, 2826, 2827	Mange Medicine, Happy Jack---	2828
Dressings, wound-----	2819	Mineral solution-----	2814
See also Bandages, adhesive.		Neg-A-Pos heel plates-----	2826
Estrogenic substance-----	2822	Parenteral drugs-----	2815-2817, 2822
Geo-Mineral-----	2811, 2812	Procaine hydrochloride-----	2816
		Prophylactics-----	2820, 2821

	N. J. No.		N. J. No.
Sercaps-----	2823	Vibro-Sazh devices-----	2827
Sugretus-----	2825	Vitamin preparation (veteri-	
Sunol-----	2825	nary)-----	2830
Tendene, Dr. Gibbons'-----	2829	Water for injection-----	2815
Thiocyl-----	2817	Wonder Red, Dr. Gibbons'-----	2829
Veterinary preparations-----	2828-2830	York's Calf Scour Capsules-----	2830

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

Botanical & Marine Laborato- ries:		Killashun Sales Div., Inc.:	
Abbe Hamon Formula Nos. 2, 4, 6, 8, 11, 12, 13, 14, 15, and 16, Abbe Hamon Tea No. 18, and Abbe Hamon Pommade Cure No. 3-----	2824	prophylactics-----	2820
Crowell, G. V.:		Killian Mfg. Co.:	
Neg-A-Pos heel plates-----	2826	prophylactics-----	2820
Dailey, E. J.:		Kirk, C. F., Co.:	
Sugretus and Sunol-----	2825	procaine hydrochloride-----	2816
Dailey's Laboratories. <i>See</i> Dai- ley, E. J.		Newcomb, W. L.:	
Gelatin Products Div., R. P. Scherer Corp.:		Acid Iron Earth Water-----	2813
York's Calf Scour Capsules----	2830	Geo-Mineral-----	2811
Geo-Mineral Co.:		Pay Less Drug Stores, Inc.:	
Geo-Mineral-----	2811, 2812	Geo-Mineral-----	2812
Gibbons, Dr. P. H.:		Rona Laboratories, Inc.:	
Dr. Gibbons' Tendene and Dr. Gibbons' Wonder Red-----	2829	wound dressing-----	2819
Hampton Mfg. Co.:		Scherer, R. P., Corp. <i>See</i> Gela- tin Products Div., R. P. Sche- rer Corp.	
adhesive bandages-----	2818	Sercaps, Inc.:	
Happy Jack, Inc.:		Sercaps-----	2823
Happy Jack Sarcoptic Mange Medicine-----	2828	Shugar, Gershon:	
Harvey Laboratories, Inc.:		wound dressing-----	2819
distilled water-----	2815	Sonorol Laboratories:	
		estrogenic substance-----	2822
		Torigian Laboratories, Inc.:	
		Thiocyl-----	2817
		Vibrosazh, Inc.:	
		Vibro-Sazh devices-----	2827
		Vi-Jon Laboratories, Inc.:	
		Geo-Mineral-----	2811, 2812



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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2831-2850

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., February 6, 1950.

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*For cosmetics, actionable under the drug provisions of the Act, see Nos. 2847 (Dr. Shokunbi's F-62 Herbal Hair Growing Aid), 2848 (Old Hickory Ointment).

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

2831. Misbranding of female hormones. U. S. v. 2 Boxes * * *. (F. D. C. No. 27161. Sample No. 57787-K.)

LIBEL FILED: April 26, 1949, Southern District of California.

ALLEGED SHIPMENT: The product was shipped on or about December 13 and 27, 1948, from Summit, N. J., to San Francisco, Calif., and was reshipped on or about February 3, 1949, from San Francisco to Long Beach, Calif.

PRODUCT: 2 boxes of *female hormones* at Long Beach, Calif., in possession of the Hudson Products Co. The product was repackaged from goods shipped to this company.

LABEL, IN PART: "Female Hormones 30 0.02 mg. Tablets of Ethinyl Estradiol * * * For use when Ethinyl Estradiol is indicated for symptoms of female hormone deficiency. Suggested dosage: 0.02 mg. tablets two or three times daily until relieved * * * Caution: Take only as directed."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration, in such manner and form as are necessary for the protection of users, since the article contained ethinyl estradiol and its labeling failed to warn that use of the article may stimulate early or incipient cancer of the breast and genital system and may induce uterine bleeding; and, Section 502 (j), the article, by reason of its ethinyl estradiol content, was dangerous to health when used in the dosage and with the frequency and duration recommended in its labeling. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 26, 1949. Default decree of condemnation and destruction.

2832. Misbranding of mineral oil. U. S. v. 72 Bottles * * *. (F. D. C. No. 27188. Sample No. 46141-K.)

LIBEL FILED: May 6, 1949, Southern District of Iowa.

ALLEGED SHIPMENT: On or about February 24, 1949, by the Halitosine Co., from St. Louis, Mo.

PRODUCT: 72 1-pint bottles of *mineral oil* at Keokuk, Iowa.

LABEL, IN PART: "Domino Mineral Oil U. S. P. Extra Heavy * * * Directions * * * infants * * * ½ teaspoonful * * * Prepared by Domino Products Co. St. Louis, Mo.—Dallas, Texas."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the article failed to bear such adequate warnings against use by children where its use may be dangerous to health and against unsafe dosage and methods and duration of administration, in such manner and form as are necessary for the protection of users. The labeling of the article failed to warn that the article should not be taken at any time other than bedtime or administered to infants except on advice of a physician.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed,

recommended, and suggested in its labeling, namely, "Directions * * * infants * * * $\frac{1}{2}$ teaspoonful," since mineral oil when given to infants sometimes is aspirated and causes lipoid pneumonia.

DISPOSITION: June 30, 1949. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2833. Misbranding of Colusa Natural Oil and Colusa Natural Oil Capsules.

U. S. v. 6 Boxes, etc. (and 49 other seizure actions). (F. D. C. Nos. 19860, 20664, 23073, 23159, 23187, 23196, 23458, 23461, 23463 to 23465, incl., 23468 to 23470, incl., 23482, 23485, 23488, 23491, 23492, 23494, 23497, 23505, 23506, 23509, 23513, 23538, 23540, 23557, 23642, 23643 to 23645, incl., 23647, 23658 to 23660, incl., 23663, 23666, 23684, 23705, 23733, 23857, 23904, 23910, 24187, 24720, 24884, 25159. Sample Nos. 5562-H, 18148-H, 39030-H to 39035-H, incl., 52854-H, 52855-H, 60624-H, 60625-H, 60634-H, 60635-H, 65790-H to 65800-H incl., 65861-H to 65864-H, incl., 66104-H, 66105-H, 66458-H, 66459-H, 66465-H to 66468-H, incl., 66471-H, 66472-H, 66474-H, 66475-H, 66495-H, 66496-H, 66499-H, 66500-H, 66595-H to 66598-H, incl., 66621-H to 66627-H, incl., 66667-H, 66668-H, 66686-H, 66687-H, 66757-H, 66758-H, 68286-H, 68287-H, 69962-H to 69965-H, incl., 69971-H, 69972-H, 73737-H, 73738-H, 74775-H, 74776-H, 76957-H, 76960-H, 77910-H, 77911-H, 77924-H, 77925-H, 78016-H to 78018-H, incl., 79503-H, 79504-H, 82708-H to 82711-H, incl., 83507-H to 83510-H, incl., 84862-H, 84863-H, 87017-H, 87018-H, 87614-H, 87615-H, 87722-H, 89528-H, 89529-H, 91200-H, 92021-H, 92022-H, 4462-K, 4463-K, 6001-K, 6002-K, 13025-K, 13026-K, 15504-K, 15914-K, 18822-K, 18823-K, 22430-K, 22431-K, 22926-K, 22927-K, 22947-K.)

LIBELS FILED: Between May 14, 1946, and July 9, 1948, Northern and Southern Districts of Ohio, Northern District of Illinois, Southern District of California, District of Kansas, Western District of Washington, District of Minnesota, Eastern and Western Districts of New York, Eastern, Middle, and Western Districts of Pennsylvania, District of Delaware, District of New Jersey, District of Montana, District of Connecticut, District of Vermont, Western District of Wisconsin, District of South Dakota, Western and Eastern Districts of Michigan, Southern District of Indiana, District of Oregon, District of Massachusetts, and Northern District of Alabama.

ALLEGED SHIPMENT: Between the approximate dates of October 5, 1945, and July 6, 1948, by the Colusa Remedy Co., from Los Angeles and Hollywood, Calif., Chicago, Ill., and Philadelphia, Pa. The Philadelphia shipment was a return shipment.

PRODUCT: 4,383 bottles of *Colusa Natural Oil* and 3,890 bottles and 20 boxes of *Colusa Natural Oil Capsules* at Zanesville, Cincinnati, East Liverpool, and Dayton, Ohio; Rockford and Chicago, Ill.; Los Angeles, Calif.; Parsons, Kans.; Tacoma and Everett, Wash.; Austin, Minn.; Buffalo and Brooklyn, N. Y.; Kingston, Chester, West Chester, Conshohocken, Norristown, Phoenixville, Lansdale, Bethlehem, Allentown, Tamaqua, Lebanon, Pittsburgh, Greensburg, Sayre, Philadelphia, and Reading, Pa.; Wilmington, Del.; Bridgeton, Vineland, Woodbury, Midland Park, New Brunswick, Atlantic City, and Bloomfield, N. J.;

*See also Nos. 2831, 2832.

Great Falls, Mont.; Ansonia, Conn.; St. Albans, Vt.; Superior, Wis.; Aberdeen, S. Dak.; Flint, Grand Rapids, and Detroit, Mich.; Terre Haute, Ind.; Salem, Oreg.; Boston, Mass.; and Birmingham and Anniston, Ala.

The oil was contained in 2-ounce and 4-ounce bottles, and the capsules were contained in 100-capsule and 200-capsule bottles and 200-capsule boxes. Examination showed that the products consisted of crude petroleum oil.

LABEL, IN PART: "Colusa Natural Oil."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on a number of the bottle labels and in circulars headed "Colusa Remedy Co. * * * General Offices * * * Los Angeles 28, Calif." accompanying certain portions of the articles, together with pictures in the circulars of skin conditions before and after using the articles, were false and misleading. The statements and pictures represented and suggested that the articles, when taken individually or in combination, were effective in the treatment of psoriasis, eczema, leg ulcers, athlete's foot, open sores, poison ivy, poison oak, and acne. The articles were not effective for such purposes.

Further misbranding, Section 502 (f) (1), the labeling of portions of the articles failed to bear adequate directions for use since the directions appearing in the labeling failed to state the disease conditions or conditions for which the articles were to be used in accordance with the directions.

DISPOSITION: Between June 28, 1946, and November 4, 1948. Default decrees of condemnation. In some instances the products were ordered delivered to the Food and Drug Administration for experimental purposes, and in other instances they were ordered destroyed.

2834. Misbranding of Abbe Hamon Teas and Formulas. U. S. v. 3 Cans, etc. (F. D. C. No. 27330. Sample Nos. 62342-K to 62345-K, incl., 62347-K, 62348-K.)

LABEL FILED: On or about June 29, 1949, District of Rhode Island.

ALLEGED SHIPMENT: On or about September 17, 1947, and April 5 and 21, 1949, by the Botanical & Marine Laboratories, from Manchester, N. H.

PRODUCT: 2 4-ounce cans of *Abbe Hamon Formula No. 3*; 1 200-gram can of *Abbe Hamon Tea No. 5*; 2 6½-ounce cans of *Abbe Hamon Formula No. 6*; 1 130-gram can of *Abbe Hamon Tea No. 7*; 2 6¾-ounce cans of *Abbe Hamon Formula No. 11*; and 2 5¼-ounce cans of *Abbe Hamon Tea No. 19* at Central Falls, R. I., together with 24 leaflets, some being in the English language and entitled "Page upon page of proof," and some in the French language entitled "Page sur page de preuves."

LABEL, IN PART: "Abbe Hamon Formula * * * Formula No. 3 Ingredients: Bark; Frangula. Leaves; Horse Tail, Ulmaire, Woodruff, Maize Stigma. Vehicle: Hazel Leaves," "Abbe Hamon Tea No. 5 * * * Constituent Herbs Rhamnus Frangula - Aspidium Filix Mas Punica Granatum - Cucurbita Pepo - Corylus Avellana - Liquiritia Officinalis," "The Genuine Abbe Hamon Tea * * * Formula No. 6. Ingredients: Lime, Elder and Feverfew Flowers; Poppy Petals; Oak and Mistletoe Leaves; Nenuphar and Valerian Roots; Hazel Leaves as a vehicle," "Abbe Hamon Tea No. 7 * * * Constituent Herbs Anchusa Officinalis - Papaver Rhoeas Viscum Album - Corylus Avellana - Sambucus Nigra," "Abbe Hamon Formula * * * Formula No. 11 Ingredients: Leaves; Box. Roots; Couchgrass, Patience Dock, Liquorice, Seaweed; Fucus Vesiculosus. Vehicle: Hazel Leaves," "Abbe Hamon Tea No. 19 * * *

Ingredients: Bark; Frangula. Leaves; Sage, Red Vine. Roots; Woodruff, Calamus, Solomon's Seal, Couchgrass. Vehicle: Hazel Leaves."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the above-mentioned leaflets which related to *Abbe Hamon Formula No. 3*, *Abbe Hamon Tea No. 5*, and *Abbe Hamon Formula No. 11*, were false and misleading since these articles were not effective in the treatment of the conditions, or for the purposes, stated and implied: "The No. 3 has fixed my Rheumatism * * * Tea for Arthritis No. 3 * * * helping her very much * * * your cure No. 3 for Arthritis," "Tea No. 5 * * * expel an enormous tapeworm," and "I have taken No. 11 for Arterio-Sclerosis for about 8 months, it relieved that paralyzing feeling, and the goitre I had for some 50 years is completely disappeared * * * Please send me Tea No. 11 for my Goitre."

Misbranding, Section 502 (f) (1), the labeling of *Abbe Hamon Formula No. 6*, *Abbe Hamon Tea No. 7*, and *Abbe Hamon Tea No. 19* failed to bear adequate directions for use for the purposes for which these articles were intended.

DISPOSITION: July 27, 1949. Default decree of condemnation and destruction.

2835. Misbranding of Mont-O-Min Mineral Tablets. U. S. v. 5 Bottles, etc. (F. D. C. No. 25018. Sample No. 20295-K.)

LABEL FILED: July 13, 1948, District of Nebraska.

ALLEGED SHIPMENT: The product was shipped on or about April 13, 1948, by the Necco Corp., from Los Angeles, Calif., and a number of circulars were shipped on or about May 10, 1948, by the Mont-O-Min Sales Corp., from Oakland, Calif.

PRODUCT: 5 250-tablet bottles and 24 100-tablet bottles of *Mont-O-Min Mineral Tablets* at Omaha, Nebr., together with a number of circulars entitled "Mont-O-Min." Examination showed that the product consisted essentially of calcium, phosphorus, iron, and iodine.

LABEL, IN PART: "Mont-O-Min Mineral Tablets Distributed by Mont-O-Min Sales Corporation, Oakland, California."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of arthritis, rheumatic conditions, and general debility, which were the conditions for which the article was offered in advertising sent to the distributor of the article.

DISPOSITION: June 16, 1949. The Mont-O-Min Sales Corp. having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2836. Adulteration of Geo-Mineral. U. S. v. 253 Bottles * * * (and 10 other seizure actions). (F. D. C. Nos. 27070, 27094, 27095, 27103 to 27105, incl., 27117, 27118, 27199, 27200, 27240. Sample Nos. 13521-K, 13522-K, 16940-K, 23486-K, 27701-K to 27703-K, incl., 42142-K, 46580-K, 46581-K, 46665-K.)

LABELS FILED: On or about May 3, 4, 5, 9, and 13, 1949, Eastern District of Wisconsin, Southern District of Illinois, Eastern and Western Districts of Pennsylvania, and Eastern District of Texas.

ALLEGED SHIPMENT: Between the approximate dates of January 27 and April 9, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

PRODUCT: *Geo-Mineral*. 757 bottles at Milwaukee, Wis.; 17 boxes, each containing 36 bottles, at New Castle, Pa.; 272 bottles at Bloomington, Ill.; 669 bottles at Peoria, Ill.; 995 bottles at Pittsburgh, Pa.; 2,518 bottles at Philadelphia, Pa.; and 943 bottles at Beaumont, Tex. Each bottle contained 3 fluid ounces.

LABEL, IN PART: "Geo-Mineral * * * Sole Distributor Geo-Mineral Company St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

DISPOSITION: Between June 6 and 27, 1949. Default decrees of condemnation and destruction.

2837. Adulteration of Geo-Mineral. U. S. v. 18 Cases * * *. (F. D. C. No. 27078. Sample No. 45991-K.)

LIBEL FILED: April 28, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about April 19, 1949, by McKesson & Robbins, from Peoria, Ill. This was a return shipment.

PRODUCT: 18 cases, each containing 36 3-ounce bottles, of *Geo-Mineral* at St. Louis, Mo.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

DISPOSITION: May 23, 1949. Default decree of condemnation and destruction.

2838. Adulteration of Neo-Mineral. U. S. v. 234 Bottles * * * (and 1 other seizure action). (F. D. C. Nos. 27093, 27127. Sample Nos. 19378-K, 44282-K, 44283-K.)

LIBELS FILED: May 5 and 6, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: On or about March 11 and April 6, 1949, by Guardian Drug Products, Inc., from Detroit, Mich.

PRODUCT: *Neo-Mineral*. 234 bottles at Dayton, Ohio, and 387 bottles at Cincinnati, Ohio.

Examination showed that the product was a water solution of ferric sulfate and that it was contaminated with mold.

LABEL, IN PART: (Bottle) "Neo-Mineral 3 Fluid Ounces Net Contents * * * Sole Distributor Neo-Mineral Co., Inc., Detroit 16, Mich."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

DISPOSITION: July 1 and 5, 1949. Default decrees of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2839. Adulteration of thiamine hydrochloride injection, sodium salicylate and iodide with colchicine ampuls, and physiological salt solution. U. S. v. Gotham Pharmaceutical Co., Inc. Plea of guilty. Fine, \$1,500. (F. D. C. No. 24257. Sample Nos. 1001K, 66337-H, 87813-H.)

INFORMATION FILED: October 19, 1948, Eastern District of New York, against Gotham Pharmaceutical Co., Inc., Brooklyn, N. Y.

ALLEGED SHIPMENT: On or about June 9 and 12 and August 13, 1947, from the State of New York into the States of Florida, Pennsylvania, and New Jersey.

NATURE OF CHARGE: *Thiamine hydrochloride injection* and *physiological salt solution*. Adulteration, Section 501 (b), the articles purported to be, and were represented as, drugs the names of which, "Thiamine Hydrochloride Injection" and "Physiological Salt Solution," respectively, are recognized in the United States Pharmacopoeia; and their quality and purity fell below the official standards. The standards provide that such articles must conform to the requirements for injections prescribed in the Pharmacopoeia, and the articles failed to meet those requirements for injection since they were not substantially free of undissolved material which could be detected when tested in accordance with the prescribed method; and the difference in quality and purity of the articles from the standards was not plainly stated, or stated at all, in their labeling.

Sodium salicylate and iodide with colchicine ampuls. Adulteration, Section 501 (b), the article purported to be, and was represented as, "Sodium Salicylate and Iodide with Colchicine Ampuls," the name of which is recognized in the National Formulary; and its quality and purity fell below the official standard. The standard provides that "Sodium Salicylate and Iodide with Colchicine Ampuls" must conform to the requirements for ampuls prescribed in the Formulary, whereas the article failed to meet the requirements for ampuls so prescribed since it was not substantially free from undissolved material which could be detected when tested in accordance with the prescribed method; and its difference in quality and purity from the standard was not plainly stated, or stated at all, on its label.

DISPOSITION: February 24, 1949. A plea of guilty having been entered, the court imposed a fine of \$1,500.

2840. Adulteration and misbranding of estrogenic substances. U. S. v. 6 Vials * * *. (F. D. C. No. 27162. Sample Nos. 56162-K, 56176-K.)

LIBEL FILED: On or about April 27, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about January 5, 1949, by Rare Chemicals, Inc., from Harrison, N. J.

PRODUCT: 6 10-cc. vials of *estrogenic substances* at New York, N. Y.

LABEL, IN PART: (Carton) "Estrogenic Substances Rare In Sesame Oil Natural estrogenic substances in sesame oil with 3% benzyl alcohol 1 cc - 50,000 I. U. Natural Estrogenic Substances."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article fell below that which it was represented to possess, namely, an amount of natural estrogenic substances equivalent to 50,000 International Units of estrone activity per cubic centimeter.

Misbranding, Section 502 (a), the label statement "1 cc - 50,000 I. U. Natural estrogenic substances consisting predominantly of estrone" was false and misleading as applied to the article, which contained an amount of natural estrogenic substances equivalent to not more than 37,500 International Units of estrone activity per cubic centimeter.

DISPOSITION: May 18, 1949. Default decree of condemnation and destruction.

2841. Adulteration and misbranding of theobromine, calcium lactate, nitroglycerin tablets. U. S. v. 1 Drum * * *. (F. D. C. No. 27153. Sample No. 56192-K.)

LABEL FILED: On or about April 27, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about November 19, 1946, from New Brunswick, N. J.

PRODUCT: 1 drum containing approximately 18,500 *theobromine, calcium lactate, nitroglycerin tablets* at New York, N. Y. Analysis of the product failed to reveal the presence of nitroglycerin.

LABEL, IN PART: (Drum) "Theobromine, Calcium Lactate, Nitroglycerin Tablets."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "0.0002 gms. Nitroglycerin."

Misbranding, Section 502 (a), the label statement "0.0002 gms. Nitroglycerin" was false and misleading. The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 18, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

2842. Misbranding of Tri-Estrin Tablets. U. S. v. Endocrine Co. and Herbert G. Brower. Pleas of *nolo contendere*. Fine of \$200 against company and \$1 against individual. (F. D. C. No. 24275. Sample No. 74627-H.)

INFORMATION FILED: July 12, 1948, District of New Jersey, against the Endocrine Co., a corporation, Union City, N. J., and Herbert G. Brower, president and treasurer of the corporation.

ALLEGED SHIPMENT: On or about February 4, 1947, from the State of New Jersey into the State of Massachusetts.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Estrogenic substance derived from gravid mare's urine, containing principally estrone and estradiol" was false and misleading. The statement represented and suggested that the estrogenic material present in the article consisted of estrogenic substance as it naturally occurs in, and is extracted from, gravid mare's urine, whereas the estrogenic material present in the article did not

*See also Nos. 2833, 2834, 2840, 2841.

consist of estrogenic substance as it naturally occurs in, and is extracted from, gravid mare's urine.

DISPOSITION: July 18, 1949. Pleas of nolo contendere having been entered, the court imposed a fine of \$200 against the corporation and a fine of \$1 against the individual.

2843. Misbranding of Boil-Tea Nettle Leaf, Alpha Tablets, Min-So Tablets, D. I. M. Tablets, Calci-Co Tablets, and Yugetun. U. S. v. Lilly Deschauer (National Herb Co.), and Ethel C. Grover. Pleas of guilty. Fine of \$200 and costs against defendant Deschauer; imposition of sentence suspended against defendant Grover, who was placed on probation for 1 year. (F. D. C. No. 24277. Sample Nos. 15506-K to 15511-K, incl.)

INFORMATION FILED: September 29, 1948, Northern District of Illinois, against Lilly Deschauer, trading as the National Herb Co., Maywood, Ill., and Ethel C. Grover, manager of the business.

ALLEGED SHIPMENT: On or about September 26, 1947, from the State of Illinois into the State of Michigan.

PRODUCT: Analyses disclosed that the *Boil-Tea Nettle Leaf* consisted of dry, green leaf and stem fragments, containing, per gram, 1.14 mg. of iron and 29 mg. of calcium; that the *Alpha Tablets* consisted essentially of plant material, containing, per tablet, 1.1 mg. of iron and 1.7 mg. of calcium; that the *Min-So Tablets* contained, per 16 tablets, 7.3 mg. of iodine, 53 mg. of iron, and 545 mg. of calcium; that the *D. I. M. Tablets* contained, per 16 tablets, 3.6 mg. of iodine, 11.2 mg. of iron, 291 mg. of calcium, and 323 mg. of phosphorus and unidentified vegetable material, and combined sodium and magnesium; that the *Calci-Co Tablets* contained, per 16 tablets, 7.8 mg. of iodine, 6.1 mg. of iron, 475 mg. of calcium, and 384 mg. of phosphorus, together with combined sodium, potassium, magnesium, and chlorine; and that the *Yugetun* consisted of an aqueous solution of ammonium alum and plant material, sediment consisting chiefly of plant material, and a calcium content of 9.4 mg. per 100 cc.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling, namely, in a booklet entitled "National Rainbow Booklet," which accompanied the articles, were false and misleading. These statements represented and suggested:

That the *Boil-Tea Nettle Leaf* would be efficacious in the treatment of boils and in the prevention of local infections, and that the *Alpha Tablets* would be efficacious in the treatment of obesity, whereas the articles would not be efficacious for such purposes;

That the *Min-So Tablets* would be efficacious in the cure, mitigation, and treatment of hardening of the arteries, arthritis, rheumatism, stiff joints, neuritis, acidosis, and kidney and bladder stones; that the article would be efficacious in the treatment and prevention of apoplexy and high blood pressure; that aging could be retarded by use of the article; and that when used in conjunction with vitamin C and another product known as "Yugetun," it would be efficacious in the treatment of varicose veins. The article would not be efficacious for the purposes represented; aging could not be retarded by its use; and when used in conjunction with vitamin C and *Yugetun*, it would not be efficacious in the treatment of varicose veins;

That the *D. I. M. Tablets* contained 273.74 calories per gram; that the article would be efficacious in the cure, mitigation, and treatment of diabetes; that

it would be efficacious to reduce and prevent hyperglycemia; that it would reduce and abolish glycosuria in diabetic patients; that it would be efficacious to heal wounds and to stabilize the blood sugar; that its use would enable diabetics to do without the use of insulin; and that there is a difference of opinion among qualified medical and nutritional experts with reference to the representations in the labeling as to the curative and therapeutic value of the article. The article contained less than 273.74 calories per gram; it would not be efficacious for the purposes represented; and there is no difference of opinion among qualified medical and nutritional experts with reference to the representations indicated;

That the *Calci-Co Tablets* would be efficacious in the cure, mitigation, and treatment of poor teeth, nervousness, rickets, stomach ulcers, stunted growth, flabby muscles, loss of blood coagulating power, tuberculosis, weak lungs, susceptibility to colds, weak heart, indigestion, irritability, sleeplessness, female troubles, malnutrition, anemia, acidosis, eczema, general run-down condition, asthma, and dropsy; that when used alone or in conjunction with vitamin C, the article would be efficacious in the cure, mitigation, and treatment of sinus trouble, and would be efficacious in purifying, enriching, and normalizing the blood stream; and that there is a difference of opinion among qualified medical and nutritional experts with reference to the representations in the labeling as to the curative and therapeutic value of the article. The article would not be efficacious for the purposes represented, and when used alone or in conjunction with vitamin C, it would neither be efficacious in the cure, mitigation, and treatment of sinus trouble, nor be efficacious in purifying, enriching, and normalizing the blood stream; and there is no difference of opinion among qualified medical and nutritional experts with reference to the representations indicated;

That the *Yugetun* would be efficacious in the cure, mitigation, and treatment of Bright's disease, frequent urination during day and night, albumin in urine, some fever, pain over the loins, dry tongue, progressive weakness, headaches, indigestion, puffiness under the eyes, shortness of breath, diseases of the blood, anemia, leukemia, syphilis, tuberculosis, symptoms of blood diseases, skin scratches, heart palpitation, flabby flesh, pale skin, a tired, listless, languid feeling, excessive weight, irritability, supersensitivity, disturbance in stomach gastric secretions, lack of aggressiveness and ambition, diseased tonsils and teeth and other disorders due to low resistance, chlorosis, lassitude, capricious appetite, indigestion, constipation, general run-down condition, underweight, amenorrhea, lack of healthy color in lips, eyelids, earlobes, and gums, lack of strength, dizziness, loss of appetite, yellow, waxy skin, and lead poisoning; and that the article when used in conjunction with *Min-So Tablets* and vitamin C, would be efficacious in the cure, mitigation, and treatment of symptoms of varicose veins. The article would not be efficacious in the cure, mitigation, and treatment of the aforesaid conditions; and when used in conjunction with *Min-So Tablets* and vitamin C, it would not be efficacious in the cure, mitigation, and treatment of symptoms of varicose veins.

DISPOSITION: Lilly Deschauer entered a plea of guilty in the United States District Court for the Northern District of Illinois, and on February 28, 1949, was fined \$200 and costs; Ethel C. Grover entered a plea of guilty in the United States District Court for the Southern District of California, and on

March 3, 1949, the court suspended the imposition of sentence and placed the defendant on probation for 1 year.

2844. Misbranding of Raymond K. Auville's Ultra Natural Health Food Combination No. 4. U. S. v. 3 Cartons * * *. (F. D. C. No. 23902. Sample No. 6204-K.)

LIBEL FILED: November 7, 1947, Western District of Pennsylvania.

ALLEGED SHIPMENT: During July 1947, by Raymond K. Auville, from Kerens, W. Va.

PRODUCT: 3 3-ounce cartons of *Raymond K. Auville's Ultra Natural Health Food Combination No. 4* at South Heights, Pa.

LABEL, IN PART: "Raymond K. Auville's Ultra Natural Health Food Combination No. 4—New Formula * * * Contents: Approximate measurement of ingredients; wild cherry leaves, three parts; wild Indian heart leaves, one part; walnut leaves, one part; wild cherry bark, two parts; may apple root, one part; red root, one half one part; red root, trace; vine fern, one half one part; alum root, one half one part; prickly ash bark, trace."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Health Food * * * Natural Health Food * * * nutritional aid for the naturalization of the blood stream" were false and misleading since the article would not maintain health in those who are healthy or restore health to those who are unhealthy, and it would not make natural the blood stream.

DISPOSITION: September 21, 1949. Default decree of condemnation and destruction.

2845. Misbranding of Rocky Dell Water. U. S. v. 104 Bottles, etc. (F. D. C. No. 27262. Sample No. 24775-K.)

LIBEL FILED: May 24, 1949, Southern District of Iowa.

ALLEGED SHIPMENT: By Rocky Dell Springs, Inc., from Woodman, Wis. The product was shipped on or about March 31, 1949, and a number of small leaflets were shipped in October 1947.

PRODUCT: 104 ½-gallon bottles of *Rocky Dell Water* at Davenport, Iowa, in possession of Harry B. Sulzer, together with 300 small leaflets entitled "Let Nature Help You," which were shipped as described above, and 600 large leaflets with the same title, which were printed locally for Mr. Sulzer.

LABELING, IN PART: (Leaflets) "Constituent Parts per Million Silica (SiO₂) 14.90 Iron and aluminum oxides (Fe₂O₃ and Al₂O₃) 0.60 Calcium (Ca) 49.02 Magnesium (Mg) 15.74 Sodium and Potassium (as sodium, Na) 4.50 Chloride (Cl) 2.75 Sulphate (SO₄) 10.32 Nitrate (NO₃) 2.83 Nitrate (NO₂) None Phosphate (PO₄) 0.24 Bicarbonate (HCO₃) 322.5 Total hardness 187.1 Dissolved solids 271.0."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the small leaflets were false and misleading since they represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of kidney and bladder trouble and many common ailments caused from such disorders, whereas the article would not be efficacious for such purposes. The article was misbranded in these respects when introduced and while in interstate commerce.

Further misbranding, Section 502 (a), certain statements in the large leaflets were false and misleading since the article would neither be effective in the treatment of the conditions stated and implied nor for the purposes mentioned. The statements represented and suggested that the article would be efficacious in the treatment of rheumatism, neuritis, arthritis, stomach and kidney troubles, and "breakdown ailments"; that it would be of value to one easily fatigued, inclined to headaches, and becoming more and more irritable; that it would be efficacious in the treatment of constipation, colds, and stomach upsets; that it would combat acidosis and activate the kidneys, intestines, lungs, and skin; that it would enable one to be young at forty, vigorous at fifty, and full of vitality in the sixties and seventies; that it would ward off high blood pressure, "breakdown ailments," and old age diseases; that it would keep one's blood clean and wholesome; the kidneys and liver active, and the intestines regularly flushed; that it would be efficacious in the prevention of pneumonia, influenza, tuberculosis, stomach troubles, diabetes, neurasthenia, dangerous kidney and bladder troubles, rheumatism, neuritis, gout, arthritis, and high blood pressure; that it would relieve irritation and pain of cystitis and burning bladder; that it was a normalizer; that it would keep one healthy, happy, and full of energy; and that it would be efficacious in the treatment of lumbago, neuralgia, stomach ulcers, and headaches. The article was misbranded in these respects while held for sale after shipment in interstate commerce.

DISPOSITION: July 12, 1949. Default decree of condemnation and destruction.

2846. Misbranding of Veronica Water. U. S. v. 120 Bottles, etc. (F. D. C. No. 24876. Sample No. 26698-K.)

LABEL FILED: June 7, 1948, Eastern District of Missouri.

ALLEGED SHIPMENT: By Veronica Sales Co., Ltd. The product was shipped on or about February 2, 1948, from Memphis, Tenn., and a number of circulars were shipped on or about February 1, 1948, from Santa Barbara, Calif.

PRODUCT: 120 1-quart bottles of *Veronica Water* at St. Louis, Mo., together with a number of circulars entitled "Arthritis Routed by Ancient California Mineral Water" and a number of circulars entitled "Veronica Water." Analysis showed that the product was a saline water containing approximately 12 grams of magnesium sulfate and 6 grams of sodium sulfate (calculated as anhydrous salts) per liter, with smaller proportions of other mineral constituents, including a therapeutically inconsequential proportion of calcium bicarbonate.

LABEL, IN PART: "Veronica California Natural Springs Water * * * Distributed by Veronica Sales Company Ltd., Santa Barbara, California."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading. The statements represented and suggested that the article was an appropriate and adequate treatment for arthritis, rheumatism, high blood pressure, acidity, and excess acidity; disorders of the stomach, intestines, kidneys, liver, and gall bladder; and stomach ulcers, athlete's foot, burns, cuts, sprains, inflammation, poison oak, skin disorders, and gallstones. The article was not an appropriate and adequate treatment for such conditions.

DISPOSITION: July 6, 1948. Default decree of condemnation and destruction.

2847. Misbranding of Dr. Shokunbi's F-219 Asthma Aid, Dr. Shokunbi's Tree of Life F-218, Dr. Shokunbi's F-62 Herbal Hair Growing Aid, and Dr. Shokunbi's F-214 Nervine. U. S. v. 10 Bottles, etc. (F. D. C. No. 27220. Sample Nos. 19324-K to 19327-K, incl.)

LABEL FILED: May 17, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: On or about February 23 and March 3, 1949, by the African Herb & Chemical Co., from Memphis, Tenn.

PRODUCT: 10 bottles of *Dr. Shokunbi's F-219 Asthma Aid*, 9 bottles of *Dr. Shokunbi's Tree of Life F-218*, 12 jars of *Dr. Shokunbi's F-62 Herbal Hair Growing Aid*, and 30 bottles of *Dr. Shokunbi's F-214 Nervine* at Cleveland, Ohio.

LABEL, IN PART: "Dr. Shokunbi's F-219 Asthma Aid * * * Net Contents 12 Fluid Oz. * * * This tonic contains the following herbs: Hore Hound, Mullen Leave, Peppermint Leave, Wild Plum Bark, Wild Cherry Bark, Lemon, Peach Leave, Colts Foot, Boneset, Pure Honey, Catnip, Skull Cap, Vavian, Corriander Seed"; "Dr. Shokunbi's Tree of Life F-218 * * * Net Contents 12 Fluid Oz. * * * Yellow Dock, Burdock Root, Poke Root, Buchu Leaves, Peppermint Leaves, May Apple, Juniper Berries, Black Snake Root, Samson Root, Wild Plum Bark, Wild Cherry Bark, Skull Cap, Fever Few, Lady Slipper, Senna, Figs"; "Dr. Shokunbi's F-62 Herbal Hair Growing Aid * * * Contents 4 Oz. * * * Ingredients Sage Leaves Extract, Jaborandie Extract, Yellow Dock Root Oil, Hair Cap Moss, Olive Oil, Fresh Eggs, Salicylic Aid-Preservative"; and "Dr. Shokunbi's F-214 Nervine * * * Ingredients Blue Skull Cap, Valarin, Catnip, Lady Slipper, Corriander Seed, Capsicum * * * Net Contents 4 Oz."

NATURE OF CHARGE: *Dr. Shokunbi's F-219 Asthma Aid*. Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not effective for the relief of discomforts of asthma, chronic bronchitis, and hay fever, was not effective as an aid in the treatment of persistent coughs with congestion or irritation of the throat, and was not effective as a tonic: "Asthma Aid Indicated for the relief of discomforts of such ailments as Asthma, Chronic Bronchitis and Hay Fever. As an aid in the treatment of Persistent Coughs with Congestion or Irritation of the Throat * * * Tonic."

Dr. Shokunbi's Tree of Life F-218. Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not effective for the purposes stated and implied and was not effective in the treatment of the diseases and conditions mentioned: "Tree of Life * * * General Tonic For Men And Women Indicated for the relief of such ailments as High Blood or Low Blood Pressure; Kidney and Bladder, Rheumatic Pain, Gas on Stomach, Nervousness, Cough Due to Cold, Chronic Bronchitis, Asthma, Arthritis, Backache."

Dr. Shokunbi's F-62 Herbal Hair Growing Aid. Misbranding, Section 502 (a), the label statement "Hair Growing Aid" was false and misleading since the article was not effective as a hair growing aid.

Dr. Shokunbi's F-214 Nervine. Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not effective for the temporary relief of discomfort of simple or ordinary nervous debility, hysteria, melancholia, neurasthenia, overwork, brain fatigue, etc., and was not effective as a general tonic: "Nervine Indicated for the temporary relief of

discomfort for symptoms known as simple or ordinary nervous debility, hysteria, melancholia, neurasthenia, overwork, brain fatigue, etc., and as a general tonic."

DISPOSITION: July 15, 1949. Default decree of condemnation and destruction.

2848. Misbranding of Old Hickory Ointment. U. S. v. 132 Jars, etc. (F. D. C. No. 26952. Sample No. 1137-K.)

LIBEL FILED: On or about April 8, 1949, Northern District of Georgia.

ALLEGED SHIPMENT: On or about January 31, 1949, by the Old Hickory Medicine Co., from Chattanooga, Tenn.

PRODUCT: 132 ½-ounce jars and 66 1-ounce jars of *Old Hickory Ointment* at Atlanta, Ga. Analysis showed that the product consisted essentially of zinc oxide, salicylic acid, carbolic acid, calomel, camphor, and menthol, in an ointment base.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not effective in the treatment of conditions represented: (Both jar sizes) "Acne, Barber's Itch, Tetter * * * Eczema, Scabies * * * Poison Oak" and (½-ounce size jar) "Dandruff * * * Poison Ivy."

DISPOSITION: May 16, 1949. Default decree of condemnation and destruction.

2849. Misbranding of Glo Oscillating Massager. U. S. v. 38 Devices, etc. (F. D. C. No. 27357. Sample No. 27718-K.)

LIBEL FILED: June 28, 1949, Southern District of Illinois.

ALLEGED SHIPMENT: By Glo Industries, Inc., from Brooklyn, N. Y. The devices and a number of placards were shipped on or about June 1, 1949, and a metal placard and a number of leaflets and catalog sheets were shipped on or about May 15 and 28 and June 6, 1949.

PRODUCT: 38 *Glo Oscillating Massagers* at Springfield, Ill., together with a metal placard entitled "Free Demonstration," 3 placards entitled "Glo for Health and Beauty," and a number of leaflets entitled "Glo for health . . . for Beauty," and 3 catalog sheets entitled "Glo The Only Instrument." The device consisted of a dome-shaped plastic case with a handle attached through which an electric connecting cord entered the dome. A vibrator and a heating unit were inside the dome.

LABEL, IN PART: "Glo Oscillating Massager With Infra-Red Heat."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling accompanying the article were false and misleading. These statements represented and suggested that the device was an effective treatment for sprains, many common discomforts, sprained nerves, aches and pains, cold miseries, aches and pains of colds, chest congestion, sinusitis, congestion, rheumatism, arthritis, neuritis, and cramps; that it would be effective to stop pain; that the heat of the device penetrates deep down into the tissues of the body to relieve pains and misery; and that its use would insure healthy circulation of blood in the facial muscles and tissue. The article would not fulfill the promises of benefit stated and implied.

DISPOSITION: July 21, 1949. Default decree of condemnation and destruction.

2850. Misbranding of ultraviolet ray devices. U. S. v. 16 Devices, etc. (F. D. C. No. 26972. Sample No. 41216-K.)

LIBEL FILED: May 5, 1949, Western District of Washington.

ALLEGED SHIPMENT: Between the approximate dates of August 18, 1948, and January 14, 1949, by H. T. Chenoweth and the Lawndale Laboratories, from Los Angeles, Calif.

PRODUCT: 16 *ultraviolet ray devices* at Seattle, Vashon, Kent, and Renton, Wash., together with a number of leaflets entitled "Ultra Violet Ray & Radiation Treatments" and "Violet Ray and Electric Radiation," which were in possession of Mahdah Brown of Seattle, Wash. Some of the leaflets were received from H. T. Chenoweth on or about March 4, 1949, in response to a request of Mahdah Brown, and other leaflets were received prior to that date. The device consisted of a high voltage mercury vapor discharge tube and transformer.

LABEL, IN PART: "R & R Ultra Violet Ray and Radiation Instrument For Therapeutic Use."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets were false and misleading. These statements represented and suggested that the devices would be beneficial in upbuilding the body; that they would stimulate the activity in the glands and tissues of the body and cause improved circulation in the blood stream; that they would make the user well, strong, and full of life and energy; that they would relieve distress and discomfort from aches and pains; that they would aid in building red corpuscles; that they would stimulate sluggish metabolism and relieve congestion; that they would stimulate bodily activity, improve digestion and elimination, restore bowel activity to normal, and cause restful sleep; and that they would be effective in the treatment of arthritis, rheumatism, sinus, asthma, high or low blood pressure, varicose veins, poor circulation, and other ills. The devices would not be effective in the treatment of such conditions. The devices were misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: June 6, 1949. Mahdah Brown, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling under the supervision of the Federal Security Agency.

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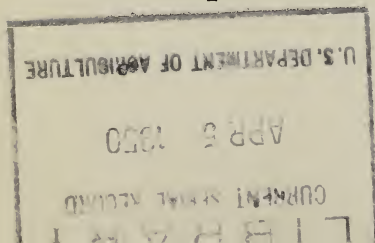
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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2851-2870

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., March 13, 1950.

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**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN
USED ACCORDING TO DIRECTIONS**

2851. Adulteration and misbranding of dextrose in isotonic solution of three chlorides (Ringer's solution), and dextrose in isotonic solution of sodium chloride. U. S. v. Cutter Laboratories, Inc. Plea of nolo contendere. Fine, \$600. (F. D. C. No. 26708. Sample Nos. 350-K, 745-K, 746-K, 10453-K, 10454-K, 16248-K to 16250-K, incl., 16252-K, 24622-K, 36797-K.)

INFORMATION FILED: May 25, 1949, Northern District of California, against Cutter Laboratories, Inc., Berkeley, Calif.

ALLEGED SHIPMENT: Between the approximate dates of October 16, 1947, and March 18, 1948, from the State of California into the States of Georgia, Florida, New Jersey, Illinois, and Washington.

NATURE OF CHARGE: Adulteration, Section 501 (b), the *dextrose in isotonic solution of sodium chloride* purported to be, and was represented as, "Dextrose and Sodium Chloride Injection," a drug the name of which is recognized in the U. S. Pharmacopoeia, and its quality and purity fell below the official standard since it was not sterile but was contaminated with viable micro-organisms; and the difference in quality and purity of the article from the standard was not plainly stated or stated at all on its label.

Adulteration, Section 501 (c), the purity and quality of the *dextrose in isotonic solution of three chlorides (Ringer's solution)* fell below that which it purported and was represented to possess since it purported and was represented to be sterile and suitable and appropriate for intravenous administration, whereas it was not sterile and was not suitable and appropriate for intravenous administration since it was contaminated with viable micro-organisms.

Misbranding, Section 502 (a), the statement "A safe, sterile * * * solution" borne on the labels of the articles was false and misleading since the articles were not sterile and were not safe for use since they were contaminated with viable micro-organisms; and, Section 502 (j), the articles were dangerous to health when used in the dosage and with the frequency and duration suggested in the labeling since the articles were contaminated with viable micro-organisms.

DISPOSITION: June 24, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$600.

2852. Misbranding of syrup urethane. U. S. v. 9 Jugs, etc. (F. D. C. No. 26859. Sample No. 34272-K.)

LABEL FILED: March 14, 1949, Northern District of California.

ALLEGED SHIPMENT: On or about October 29 and November 17 and 27, 1948, and January 10, 1949, by Marvin R. Thompson, Inc., from Stamford, Conn.

PRODUCT: 9 1-gallon jugs and 24 1-pint bottles of *syrup urethane* at San Francisco, Calif.

LABEL, IN PART: "Syrup Urethane-M. R. T. * * * Each Teaspoonful (5-cc) contains Urethane 4 Grs. in a Flavored Syrup Base. Directions: 1 teaspoonful every 3 or 4 hours, or as directed by the physician."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling, namely, "1 teaspoonful every 3 or 4 hours," since administration of 1 teaspoonful every 3 or 4 hours is capable of causing leucopenia.

The article also was in violation of Section 505 (a) since it was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: November 14, 1949. Marvin R. Thompson, Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2853. Misbranding of benadryl capsules, Dexedrine sulfate tablets, sulfathiazole lozenges, and nembutal and aspirin capsules. U. S. v. Charles E. Prescott (Prescott Drug Store). Plea of *nolo contendere*. Fine, \$1,000. (F. D. C. No. 26718. Sample Nos. 27056-K, 45894-K, 46419-K, 46422-K.)

INFORMATION FILED: July 8, 1949, Western District of Tennessee, against Charles E. Prescott, trading as the Prescott Drug Store, Memphis, Tenn.

INTERSTATE SHIPMENT: Between the approximate dates of February 17 and December 8, 1948, of one lot of *benadryl capsules*, from St. Louis, Mo.; one lot of *Dexedrine sulfate tablets*, from Philadelphia, Pa.; 1 lot of *sulfathiazole lozenges*, from Indianapolis, Ind.; and 1 lot of *nembutal and aspirin capsules*, from Chicago, Ill.

ALLEGED VIOLATION: On or about January 14, 15, 17, and 18, 1949, and while the articles were being held for sale after shipment in interstate commerce, the defendant caused quantities of the articles to be removed from the bottles in which they had been shipped, and repacked and sold them to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded. When shipped in interstate commerce, the articles bore on their labels the prescription legend prescribed by the regulations. The quantities of the articles which were repacked and sold by the defendant were labeled, "Benadryl Capsules 50 Mg. [or "Sulfathiazole Lozenges" or "Nembutal & Aspirin"] Prescott Drugs, Memphis Tennessee" and "Dexedrine Sulfate Tablets."

NATURE OF CHARGE: Misbranding Section 502 (b) (2), the repackaged articles bore no label containing a statement of the quantity of the contents; and, Section 502 (f) (1), they failed to bear labeling containing adequate directions for use.

Further misbranding, Section 502 (b) (1), the *Dexedrine sulfate tablets* bore no label containing the name and place of business of the manufacturer, packer, or distributor. Section 502 (d), the *nembutal and aspirin tablets* were a drug for use by man and contained a chemical derivative of barbituric acid, which derivative has been found by the Administrator of the Federal Security Agency, after investigation, to be, and by regulations designated as, habit-forming; and the labels of the repackaged *nembutal and aspirin capsules* failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement, "Warning—May be habit forming";

and, Section 502 (f) (2), the repackaged *sulfathiazole lozenges* bore no labeling containing warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: July 22, 1949. A plea of *nolo contendere* having been entered, the court imposed a fine of \$1,000.

2854. Misbranding of *seconal sodium capsules*, *phenobarbital tablets*, *amytal tablets*, *Dexedrine sulfate tablets*, and *diethylstilbestrol tablets*. U. S. v. Kay Surgical, Inc., and Thomas M. Wardlaw. Pleas of *nolo contendere*. Fine of \$1,000 against corporation and \$250 against individual. (F. D. C. No. 26714. Sample Nos. 27054-K, 27059-K, 46417-K, 46418-K, 46423-K to 46425-K, incl.)

INFORMATION FILED: July 8, 1949, Western District of Tennessee, against Kay Surgical, Inc., and Thomas M. Wardlaw, a pharmacist for the corporation.

INTERSTATE SHIPMENT: Between the approximate dates of December 29, 1947, and December 28, 1948, from Indianapolis, Ind., and Philadelphia, Pa., of 3 lots of *seconal sodium capsules*, 1 lot of *phenobarbital tablets*, 1 lot of *amytal tablets*, 1 lot of *Dexedrine sulfate tablets*, and 1 lot of *diethylstilbestrol tablets*.

ALLEGED VIOLATION: On or about January 14, 15, 17, and 19, 1949, and while the articles were being held for sale after shipment in interstate commerce, the defendants caused quantities of the articles to be removed from the bottles in which they had been shipped, and repacked and sold them to various persons without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded. When shipped in interstate commerce, the articles had borne on their labels the prescription legend prescribed by the regulations. With the exception of one lot of *seconal sodium capsules*, the repackaged drugs were labeled, in part: "Kay Surgical, Inc. * * * Memphis, Tenn. Seconal Capsules [or "Amytal Tablets 1½ grs.," "Stilbesterol 1 mg.," "Phenobarbital 1½ grains," or "Dexedrine"]." One lot of the repackaged *seconal sodium capsules* was labeled, in part: "Kay Surgical, Inc. * * * Memphis, Tenn. 58975 1-14-49 Take one when needed Dr. Pearce."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged articles bore no label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the repackaged articles failed to bear labeling containing adequate directions for use.

Further misbranding, Section 502 (d), the *seconal sodium capsules*, the *amytal tablets*, and the *phenobarbital tablets* were drugs for use by man and contained a chemical derivative of barbituric acid, which derivative has been found by the Administrator of the Federal Security Agency, after investigation, to be, and by regulations designated as, habit-forming; and the labels of the repackaged *seconal sodium capsules* the *amytal tablets*, and the *phenobarbital tablets* failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement, "Warning—May be habit forming"; and, Section 502 (e) (1), the label on one lot of the repackaged *seconal sodium capsules* failed to bear the common or usual name of the drug.

DISPOSITION: July 22, 1949. Pleas of *nolo contendere* having been entered, the court imposed a fine of \$1,000 against the corporation and a fine of \$250 against the individual.

2855. Misbranding of seconal sodium capsules. U. S. v. Ether Ewer (Ewer Drug Co.). Plea of guilty. Fine of \$250 on first four counts of information; fine of \$500 on remaining 5 counts. Fine of \$500 suspended and defendant placed on probation for 1 year. (F. D. C. No. 26730. Sample Nos. 23131-K, 23133-K, 23135-K, 23137-K, 23139-K, 23140-K, 23517-K.)

INFORMATION FILED: September 16, 1949, Northern District of Texas, against Ether Ewer, trading as the Ewer Drug Co., Dallas, Tex.

ALLEGED SHIPMENT: Prior to the date of the sales of the *seconal sodium capsules* by the defendant, as hereinafter described, the capsules were manufactured in Indianapolis, Ind., and shipped in interstate commerce into the State of Texas.

ALLEGED VIOLATION: On or about September 1, 3, 8, 12, 16, 18, and 23, and October 13 and 14, 1948, and while a number of *seconal sodium capsules* were being held for sale after shipment in interstate commerce, the defendant caused a number of the capsules to be repackaged and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged *seconal sodium capsules* being misbranded. Each container of the repackaged capsules bore a label containing, among other things, the number of a prescription which had been previously filled by the defendant, the name of the doctor issuing such prescription, the name and address of the defendant, and certain directions for use.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the label of the repackaged *seconal sodium capsules* contained no statement of the quantity of the contents. Section 502 (d), the *seconal sodium capsules* were a drug for use by man and contained a chemical derivative of barbituric acid, which derivative has been found by the Administrator of the Federal Security Agency, after investigation, to be, and by regulations designated as, habit-forming; and the label of the repackaged *seconal sodium capsules* failed to bear the name and quantity or proportion of such derivative and, in juxtaposition therewith, the statement, "Warning—May be habit forming"; Section 502 (e) (1), the label of the repackaged capsules failed to bear the common or usual name of the drug, *seconal sodium*; and, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use since the directions appearing variously on the packages, "One as d'td," "One at bed tn," "One as need for Rest," "One as need," "One before bed time," "One at bed tim." were not adequate directions for use.

DISPOSITION: September 21, 1949. A plea of guilty having been entered, the court imposed a fine of \$250 on the first four counts of the information and a fine of \$500 on the remaining five counts. The fine of \$500 was suspended, and the defendant was placed on probation for 1 year.

2856. Action to enjoin and restrain the interstate shipment of IDU A New Skin Remedy. U. S. v. William B. Schmidt (IDU Products Co.). Temporary decree of injunction; injunction action subsequently dismissed. (Inj. 192.)

COMPLAINT FILED: On or about April 27, 1948, Western District of Wisconsin, against William B. Schmidt, trading as the IDU Products Co., at Tomahawk, Wis.

NATURE OF CHARGE: The defendant, William B. Schmidt, has been and was at the time of filing the complaint, introducing and delivering for introduction

into interstate commerce at Tomahawk, Wis., consignments of a drug designated as "IDU A New Skin Remedy," which consisted essentially of a mixture of isopropyl alcohol, small proportions of chloral hydrate, camphor, methyl salicylate, mercuric chloride, and water, and which was misbranded in the following respects:

Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article constituted an adequate treatment for irritations of the skin and scalp, eczema in all its forms, salt-rheum, itch, hives, ringworm, barber's itch, scalp troubles, tetter, erysipelas, chilblains, sores, boils, varicose ulcers, and all pustular skin eruptions, whereas the article did not constitute an adequate treatment for such disease conditions;

Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and it contained an ingredient designated on the label as "Hydrargyri Chloridum Cor"; and the label of the article did not bear the common or usual name of such ingredient, namely, corrosive sublimate, a mercury derivative;

Section 502 (f) (2), the labeling failed to bear adequate warnings against unsafe methods and duration of administration and application in such manner and form as are necessary for the protection of users, in that the article contained corrosive sublimate, a derivative of mercury; and its labeling failed to warn that use of the article may cause irritation of the skin, and that application of the article to large areas of the skin may cause serious mercury poisoning.

The complaint alleged further that unless restrained, the defendant would continue to introduce and deliver for introduction into interstate commerce the misbranded article.

PRAYER OF COMPLAINT: That the defendant be perpetually enjoined from commission of the acts complained of, and that a preliminary injunction be granted during the pendency of the action.

DISPOSITION: July 3, 1948. A temporary injunction was entered, enjoining the defendant during the pendency of the action from introducing or delivering, or causing the introduction or delivery, for introduction into interstate commerce, the article designated as "IDU A New Skin Remedy," which was misbranded as alleged in the complaint. Thereafter assurances were received from the defendant that he was disposing of the business, and, accordingly, the injunction was dismissed on May 5, 1949.

2857. Misbranding of acetophenetidin and aspirin tablets. U. S. v. 2 Drums, etc.
(F. D. C. No. 27224. Sample Nos. 57711-K to 57714-K, incl.)

LABEL FILED: May 20, 1949, Southern District of California.

ALLEGED SHIPMENT: On or about July 19, 1948, by the Suter Chemical Co., from Altoona, Pa.

PRODUCT: *Acetophenetidin and aspirin tablets.* 2 drums, each containing 250,000 tablets; 10 drums, each containing 40,000 tablets; 12 bottles, each containing 126 tablets; 36 bottles, each containing 42 tablets; 250 bottles, each containing 126 tablets; and 160 bottles, each containing 42 tablets.

LABEL, IN PART: (Drum) "From Durneck Company of Los Angeles Shipping Department 1911 Fifth Street Altoona, Pennsylvania"; (12- and 36-bottle lots) "Myrel * * * Distributed By Durneck Co., Los Angeles, Calif."; and (250- and 160-bottle lots) "Dorel * * * Distributed by Durneck Co., Los Angeles, Calif."

NATURE OF CHARGE: Misbranding, Section 502 (e) (2), the tablets in the drums were fabricated from two or more ingredients, and they failed to bear a label containing the common or usual name of each active ingredient and the quantity or proportion of acetophenetidin contained therein; and, Section 502 (f) (1), the labeling of the tablets in the drums failed to bear adequate directions for use.

Further misbranding, Section 502 (a), certain statements on the bottle labels of the "Myrel" and "Dorel" tablets were false and misleading. These statements represented and suggested that the tablets would be effective in the palliative relief of muscular aches and pains associated with rheumatism, arthritis, neuralgia, neuritis, sciatica, and lumbago; and that the tablets which were labeled "Myrel" would be effective in the treatment of certain forms of lowered vitality associated with rheumatism, arthritis, neuralgia, neuritis, sciatica, and lumbago, and in the treatment of the systemic disturbance of insufficiency of certain vital elements, sometimes found in those conditions. The tablets would not be effective in the treatment of such conditions.

DISPOSITION: August 18, 1949. Default decree of condemnation and destruction.

2858. Misbranding of Vit-An-Min. U. S. v. 240 Cartons * * *. (F. D. C. No. 27151. Sample No. 20028-K.)

LIBEL FILED: On or about April 29, 1949, Western District of Missouri.

ALLEGED SHIPMENT: On or about April 1 and 5, 1949, by S. & R. Laboratories, Inc., from Chicago, Ill.

PRODUCT: 240 11½-ounce cartons of *Vit-An-Min* at Kansas City, Mo.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "Here's To Your Health" were false and misleading since they represented and suggested that common food cannot be relied upon to supply the vitamins and minerals essential to man for normal health, whereas there is no difficulty in obtaining the vitamins and minerals needed by consumption of common foods.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: August 30, 1949. Default decree of condemnation and destruction.

2859. Misbranding of 5 unlabeled light devices. U. S. v. 5 Devices, etc. (F. D. C. No. 27270. Sample No. 9546-K.)

LIBEL FILED: June 7, 1949, Southern District of New York.

ALLEGED SHIPMENT: The devices were shipped on or about April 13, 1949, from Pittsburgh, Pa.

PRODUCT: 5 unlabeled *light devices* at New York, N. Y., stored to the account of D. H. Urbanik, together with 3 copies of a booklet entitled "The Science of Color." The booklets were used in connection with a sales demonstration of the devices on April 11, 1949, by Helen Houston, acting for, and in association with, D. H. Urbanik.

The device consisted of an electric light bulb in a metal box. The box was approximately 14 by 8 by 6 inches and was mounted on an adjustable stand and equipped with a lens and colored squares of gelatin-coated cellophane to cover the lens.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklets were false and misleading since the device was not effective in the treatment of the diseases, conditions, and symptoms stated and implied. The statements represented and suggested that the device was effective in the treatment of fever, inflammation, burns, suppuration, skin diseases, nervous irritability, high blood pressure, nervous disorders, neuralgia, headaches associated with high blood pressure, slow bone growth, bone fractures, coagulated blood, uncoagulated blood, slow pulse, depression, tuberculosis, extreme physical debility, headaches accompanied by low blood pressure, tiredness or depression, overexcitement, weak heart, lungs, and blood vessels, melancholia, nervous or mental disorder, peevishness, sickness and low vitality (in children), constipation, enlargement of the heart, palpitation of the heart, slow heart, angina pectoris (breast pang), arterial degeneration, influenza, acute alcoholism, arthritis, chronic rheumatism, diabetes, obesity, rickets, paralysis, hay fever, acute catarrhal laryngitis, broncho-pneumonia, tonsillitis, acute pleurisy, chronic pleurisy, neuritis, hiccough, gallstones, anemia, asthma, bronchitis, congestion of lungs, sore throat, acute gastritis, enteroptosis (prolapse), jaundice, cirrhosis of the liver, suppression of urine (anuria), sinusitis, goiter, colitis, whooping cough, retinitis (inflammation of retina), atrophy of optic nerve, sciatic neuritis, cramps, neurasthenia, varicose veins, sunstroke, nervous headache, insomnia, low blood pressure, boils and carbuncles, painful menstruation, weak memory, insufficient red blood, decay, skin troubles, insufficient white corpuscles, weak lungs, and diseases of the following glands: pituitary, thyroid, thymus, parathyroid, gonads, adrenals, pancreas, and spleen.

Further misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use for the purposes for which it was recommended by Helen Houston, its distributor, during a lecture on April 11, 1949.

The device was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 5, 1949. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2860. Adulteration and misbranding of Geo-Mineral. U. S. v. 451 Bottles, etc.
(F. D. C. No. 27008. Sample No. 44269-K.)

LIBEL FILED: April 21, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 8, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

PRODUCT: 451 bottles of Geo-Mineral at Toledo, Ohio, in possession of the Lane Drug Co., together with a number of copies of a newspaper advertisement from the Toledo Blade. Analysis showed that the product was a water solution of ferric sulfate and was contaminated with mold.

LABEL, IN PART: (Bottle) "Geo-Mineral 3 Fluid Ounces Net Sole Distributor Geo-Mineral Company, St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

Misbranding, Section 502 (a), certain statements in the newspaper advertisement were false and misleading since the article was not effective in the treatment of the diseases and conditions represented and would not fulfill the other promises of benefit stated and implied. The statements represented and suggested that the article would be effective in the treatment of stomach ailments, weak kidneys, rheumatic pains, arthritis, neuritis, headaches, nervousness, acid toxins, bloating, lack of vitality and energy, poor appetite, underweight, dizzy spells, rheumatism, kidney ailments, poor blood, lack of strength and pep, and the condition in which one is dull, tired, and lazy, with no ambition to work or play; and further, that the article would be effective to generate mental brilliance and give sparkling eyes. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 18, 1949. Default decree of condemnation and destruction.

2861. Adulteration of Neo-Mineral. U. S. v. 58 Dozen Bottles * * *. (F. D. C. No. 27075. Sample No. 18374-K.)

LABEL FILED: April 26, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: On or about March 10, 1949, by the Neo-Mineral Co., Inc., from Detroit, Mich.

PRODUCT: 58 dozen 3-ounce bottles of *Neo-Mineral* at Cincinnati, Ohio. Examination showed that the product was a water solution of ferric sulfate and was contaminated with mold.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

DISPOSITION: July 1, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2862. Adulteration of Siliform. U. S. v. Heilkraft Medical Company, Inc., and William A. L. Junker. Pleas of nolo contendere. Fine of \$50 against each defendant. (F. D. C. No. 25617. Sample Nos. 9030-K, 30961-K, 31368-K, 33286-K, 43440-K.)

INFORMATION FILED: July 1, 1949, District of Massachusetts, against the Heilkraft Medical Co., Inc., Boston, Mass., and William A. L. Junker, president and treasurer of the corporation.

ALLEGED SHIPMENT: Between the approximate dates of January 14 and June 7, 1948, from the State of Massachusetts into the State of New York, California, and Illinois.

*See also No. 2851.

LABEL, IN PART: "Siliform * * * Silicic Acid, Formic Acid and Sodium Formate in a Colloidal Solution * * * For intramuscular and subcutaneous injections."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess. The article purported and was represented to be suitable and appropriate for intramuscular and subcutaneous injection, whereas it was not suitable and appropriate for such purposes since it was not sterile but was contaminated with viable micro-organisms, and in four of the five shipments, it contained excessive undissolved material.

DISPOSITION: July 12, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$50 against each defendant.

2863. Adulteration and misbranding of adhesive strips. U. S. v. 76 Boxes * * *.
(F. D. C. No. 26986. Sample No. 11190-K.)

LIBEL FILED: On or about April 12, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about March 9, 1949, by the Hampton Mfg. Co., from Carlstadt, N. J.

PRODUCT: 76 boxes of *adhesive strips* at New York, N. Y.

LABEL, IN PART: (Box) "100 Individually Wrapped Blue Cross sterilized waterproof Adhesive Strips."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "sterilized" was false and misleading.

DISPOSITION: April 29, 1949. Default decree of condemnation and destruction.

2864. Adulteration and misbranding of prophylactics. U. S. v. 41 Gross * * *.
(F. D. C. No. 27426. Sample No. 45598-K.)

LIBEL FILED: June 17, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about May 11, 1949, by the Goodwear Rubber Co., from New York, N. Y.

PRODUCT: 41 gross of *prophylactics* at St. Louis, Mo. Examination of samples showed that 2.1 percent were defective in that they contained holes.

LABEL, IN PART: "Xcello's Prophylactics Mfd. by The Killian Mfg. Co., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statement "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: July 11, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2865. Misbranding of Paba-Liv Tablets; Toco-E Capsules; Sodium, Okra, and Celery Tablets; Amino Acids Capsules; Food Minerals Dietary Supplement; Bone Meal Tablets; 20-to-1 Liver Concentrate with Iron Capsules; Multa Vitamin Spheroid Capsules; Lecithin Capsules; Choline Chloride Tablets; B-P-D Tablets; High Potency Vitamin C Tablets; and Russian Radish and Parsley Concentrates Tablets. U. S. v. Sawall Nutritional Products, Inc. (Sawall Health Products, Inc.), and Frank A. Sawall. Pleas of nolo contendere. Fine of \$2,250 against corporation; sentence suspended against individual and individual placed on probation for 2 years. (F. D. C. No. 25612. Sample Nos. 87669-H to 87676-H, incl., 18062-K to 18070-K, incl.)

INFORMATION FILED: April 25, 1949, Eastern District of Michigan, against the Sawall Nutritional Products, Inc., formerly trading as Sawall Health Products, Inc., Detroit, Mich., and Frank A. Sawall, president of the corporation.

ALLEGED SHIPMENT: On or about March 16, 1947, and April 19, 1948, from the State of Michigan into the States of Indiana and New York.

LABEL, IN PART: "Sawall's Paba-Liv Tablets Each tablet contains: 100 Mgms. Para-Amino Benzoic Acid, 7 grs. (20-1) Liver Concentrate"; "Capsules Sawall's Toco-E * * * Each three minim capsule contains wheat germ oil and mixed natural tocopherols, equivalent in biological activity to 5 International Units or 5 Mg. Alpha Tocopherol"; "Sawall's Sodium, Okra and Celery Each tablet contains: 160 Milligrams of Dehydrated Okra, 160 Milligrams of Dehydrated Celery, 60 Milligrams of Sodium Malate"; "Capsules Sawall's Amino Acids Each capsule contains the ten essential Amino Acids in the following proportions: Lysine 10 Milligrams, Leucine 9 Milligrams, Phenylalanine 7 Milligrams, Valine 7 Milligrams, Threonine 6 Milligrams, Methionine 6 Milligrams, Isoleucine 5 Milligrams, Histidine 4 Milligrams, Tryptophane 3 Milligrams, Arginine 3 Milligrams. These are suspended in a base of 40% Protein (derived from Soy Beans), di-calcium phosphate and pepsin"; "Sawall's Food Minerals Dietary Supplement Is a composition of Minerals comprising: Calcium Carbonate, Sodium Chloride (iodized), Calcium Phosphate, Iron Sulphate, Magnesium Sulphate, Sodium Silicate, Potassium Citrate, Sodium Phosphate, Calcium Chloride, Manganese Citrate, Sulphur"; "Tablets Sawall's Bone Meal Three Tablets Daily furnish: Calcium (Ca), 1 Gram, * * * Phosphorus (P), 450 Milligrams"; "Capsules Sawall's 20-to-1 Liver Concentrate with Iron Each capsule contains 7 grains 20-1 Liver Concentrate and 20 Milligrams of Iron Reduced by Hydrogen"; "Capsules Sawall's Multa Vitamin Spheroid Capsule Each Capsule Contains: Vitamin A (Natural Ester) 5000 USP Units, Vitamin B-1 (Thiamin Chloride) 500 USP Units, Vitamin B-2 (Riboflavin) 3000 USP Micrograms, Vitamin C (Ascorbic Acid) 600 USP Units, Vitamin D (Activated Ergosterol) 1000 USP Units, Calcium Pantothenate (Dextrorotatory) 1000 Micrograms, Niacin Amide USP 10,000 Micrograms, Vitamin

*See also Nos. 2851, 2856-2860, 2863, 2864.

B-6 (Pyridoxine Chloride) 100 Micrograms, Wheat Germ Oil (Equivalent from Concentrate) Approx 160,000 Micrograms (160 Mg.) as a natural source of Vitamin E"; "Capsules Sawall's Lecithin * * * Each capsule contains: 4 Grains Soy Bean Lecithin Suspended in 3 minim pure soybean oil"; "Tablets Sawall's Choline Chloride Each tablet contains 50 Mg. Choline Chloride, 50 Mg. Inositol, 10 Mg. Methionine, in a base of 225 Mg. Liver Concentrate, and 150 Mg. DiCalcium Phosphate"; "B-P-D Tablets Each Tablet Contains: Bile Salts 1 gr., Duodenum Substance 2 grs., Pancreas 2 grs., Papaya Enzyme 2 grs., Vitamin B-1, 333 USP"; "Tablets Sawall's High Potency Vitamin C Each tablet contains: 1200 U.S.P. Units (60 Mg.) Vitamin C (Ascorbic Acid)"; and "Tablets Sawall's Russian Radish And Parsley Concentrates Each Enteric Coated Tablet Contains Russian Radish Concentrate (*Raphanus Nigra*) 6½ Grains, Parsley Concentrate 2 Grains."

NATURE OF CHARGE: *Paba-Liv Tablets, Toco-E Capsules, Sodium, Okra, and Celery Tablets, Amino Acids Capsules, Food Minerals Dietary Supplement, Bone Meal Tablets, 20-to-1 Liver Concentrate with Iron Capsules, Multa Vitamin Spheroid Capsules, and Lecithin Capsules.* Misbranding, Section 502 (a), certain statements in the accompanying labeling of the articles, namely, in a letter dated April 19, 1948, addressed to the consignee, were false and misleading. The statements represented and suggested that the articles when used as directed would be effective to overcome sterility and prevent miscarriage, whereas the articles would not be effective for such purposes.

Food Minerals, Dietary Supplement, Sodium, Okra, and Celery Tablets, Choline Chloride Tablets, B-P-D Tablets, Multa Vitamin Spheroid Capsules, 20-to-1 Liver Concentrate with Iron Capsules, High Potency Vitamin C Tablets, and Russian Radish and Parsley Concentrates Tablets. Misbranding, Section 502 (a), certain statements in the accompanying labeling of the articles, namely, on a circular headed "A Corrective Diet Suggestion," were misleading since the articles when used as directed would not be efficacious for the purposes, and would not fulfill the promises of benefits, stated and implied. The statements represented and suggested:

That the *Food Minerals Dietary Supplement* would be efficacious in the cure, mitigation, treatment, and prevention of brain and nerve disorders, fatigue, anemia, excitability, stupidity, poor teeth and bones, retarded growth, skin diseases, poor development of hair, nails, bones, and teeth, distressing toxic conditions of the stomach and nerves, flightiness, heart trouble, muscular soreness, dental caries, infections, loss of hair, poor complexion, skin infection, poor eyesight, low endurance, nerve disorders, depression, weakness, constipation, irregular heart beat, poor muscular coordination, liver trouble, poor digestion, loss in body weight, digestive troubles, acidity, irritability, deafness, catarrh, pallor, restlessness, starvation, bloating, painful joints, albuminuria, poor water retention, brooding, sleeplessness, pallid complexion, neurasthenia, goiter, worry, erratic heart, shyness, brain collapse, sterility, overweight, deformed body, lowered mental activity, sensitiveness to infections, autointoxication, hysteria, fussiness, spastic colitis, convulsions, dilation of blood vessels, confusion of mind, lack of elasticity, nerve collapse, weak respiration of tissues, growth below normal, coldness, poor nutrition, extreme leanness, laxness, growths, forgetfulness, unsightly flesh, and creepy nervous system; that the article would promote bodily cleansing, give tone to life, firmness to arteries, and strength to pulse; that it would give endurance, long life, and will power; that it would prevent premature death, and promote alkalinity, optimism, and speed; that it would immunize against tuberculosis, cancer, and nerve exhaus-

tion; that it would give energy, lustrous hair, and bright eyes; that it would heal injuries, reduce pain, balance the body and brain, and cleanse and alkalize the body; that it would keep proportions of body, maintain normal heart action, and give vitality, warmth, magnetism, creative power, and mental endurance; that it would insure a healthy complexion, protect the brain from toxins, cool and relax the body, and give to the nervous system control and recuperation; that it would enable the fibers of the brain to connect and to coordinate thoughts; and that it would adapt the nervous system to darkness.

That the *Sodium, Okra, and Celery Tablets* would be efficacious in the cure, mitigation, treatment, and prevention of loss of body weight, digestive troubles, nerve disorders, acidity, weakness, irritability, deafness, catarrh, pallor, restlessness, starvation, depression, infections, constipation, irregular heart beat, poor muscular coordination, liver trouble, poor digestion, bloating, painful joints, fear, albuminuria, poor water retention, loss of hair, poor complexion, skin infection, poor eyesight, low endurance, sleeplessness, autointoxication, hysteria, fussiness, spastic colitis, convulsions, dilation of blood vessels, skin diseases, retarded growth, poor development of hair and nails, distressing toxic conditions of the stomach and nerves, confusion of mind, lack of elasticity, nerve collapse, weak respiration of tissues, growth below normal, poor appetite, lowered resistance to infections, lack of vitality, respiratory troubles, sinus troubles, intestinal disorders, kidney ailments, skin troubles, frequent colds, poor teeth, weakened adrenal gland functioning, muscular weakness and fatigue, and drying up of tissues; that the article would promote bodily cleansing, give tone to life, promote alkalinity, optimism, and speed, and immunize against tuberculosis, cancer, and nerve exhaustion; that it would give energy, lustrous hair, and bright eyes; that it would heal injuries, reduce pain, and balance the body and brain; that it would cleanse and alkalize the body, keep calcium from hardening around the joints and the arteries, and cleanse and keep proportions of body; that it would give normal heart action, cool and relax the body, and give the nervous system control and recuperation; that it would enable the fibers of the brain to connect or to coordinate thoughts; that it would adapt the nervous system to darkness; that it would promote growth and maintain resistance to infections; that it would promote normal glandular functioning, especially for adrenal glands, lengthen the life span, and tone up the entire body; that it would maintain in good condition the membranes of the eyes and the membranes of the digestive tract and urinary tract; and that it would keep the skin in good condition;

That the *Choline Chloride Tablets* would be efficacious in the cure, mitigation, treatment, and prevention of flightiness, anemia, heart trouble, muscular soreness, dental caries, poor development of bones and teeth, brain and nerve disorders, fatigue, excitability, stupidity, poor teeth and bones, retarded growth, brooding, sleeplessness, pallid complexion, irritability, neurasthenia, starvation, confusion of mind, lack of elasticity, nerve collapse, weak respiration of tissues, growth below normal, poor functioning of mammary and adrenal glands, poor cell respiration, lack of vigor, weight loss, paralysis of intestines, nervous breakdown, cataracts, loss of hair, skin trouble, lowered general tone, nerve disturbances, mouth soreness, nausea, urinary pigmentation, constipation, skin diseases, vomiting, insanity, and tongue redness; that the article would give firmness to the arteries and strength to the pulse; that it would give endurance, long life, and will power; that it would prevent premature death, insure a healthy complexion, and give vitality, warmth, magnetism, creative power, and mental endurance; that it would enable the fibers

of the brain to connect and to coordinate thoughts; that it would adapt the nervous system to darkness; that it would prevent premature old age, promote growth, improve general health, and lengthen the life span; that it would develop a healthy skin, protect against cataracts, produce better nerve tissues, and promote better assimilation; and that it would maintain normal functioning of the gastrointestinal tract and the skin;

That the *B-P-D Tablets* would be efficacious in the cure, mitigation, treatment, and prevention of flightiness, anemia, heart trouble, muscular soreness, dental caries, poor development of bones and teeth, loss in body weight, digestive troubles, nerve disorders, weakness, acidity, irritability, deafness, catarrh, pallor, restlessness, starvation, depression, constipation, irregular heart beat, poor muscular coordination, liver trouble, poor digestion, painful joints, fear, albuminuria, poor water retention, brain disorders, fatigue, excitability, stupidity, poor teeth and bones, retarded growth, autointoxication, sleeplessness, hysteria, fussiness, spastic colitis, convulsions, dilation of blood vessels, confusion of mind, lack of elasticity, nerve collapse, weak respiration of tissues, growth below normal, poor appetite, lowered resistance to infections, lack of vitality, respiratory troubles, sinus troubles, intestinal disorders, kidney ailments, skin troubles, frequent colds, weakened adrenal gland functioning, muscular weakness and fatigue, drying up of tissues, general weakness, poor nutrition, sterility, poor glandular functioning, paralysis, lack of child growth, lack of appetite, neuritis and other nerve ailments, heart disturbances, too fast development of the thyroid, pituitary, and gonad glands, tiredness, defective teeth, poor knitting of bones, headaches, weakened blood capillaries, digestive troubles leading to gastric ulcers, weakened functioning of mammary glands, swollen limbs, hemorrhages, adrenal gland dysfunctioning, poor assimilation of calcium and phosphorus, lack of muscle tone, disintegration of teeth, deterioration of blood vessels, lack of vigor, enlarged joints, bone infection, curvature of the spine, poor functioning of mammary and adrenal glands, poor cell respiration, lack of vigor, paralysis of the intestines, nervous breakdown, cataracts, loss of hair, skin trouble, and lowered general tone; that the article would give firmness to the arteries and strength to the pulse; that it would give endurance, long life, and will power; that it would prevent premature death, cleanse and alkalize the body, and keep calcium from hardening around the joints and in the arteries; that it would heal injuries, reduce pain, balance the body and the brain, keep the proportions of the body, maintain normal heart action, and cool and relax the body; that it would give the nervous system control and recuperation, enable the fibers of the brain to connect and to coordinate thoughts, and adapt the nervous system to darkness; that it would promote growth and maintain resistance to infections; that it would promote normal glandular functioning, especially for the adrenal glands, lengthen the life span, and tone up the entire body; that it would maintain in good condition the membranes of the eyes and the membranes of the digestive tract and urinary tract; that it would keep the skin in good condition, stimulate the appetite and assimilation, promote normal nerve functioning, and destroy acids caused by tiredness; that it would promote normal glandular functioning, especially of the reproductive, adrenal, pituitary, and thymus glands; that it would promote growth of good teeth, destroy bacterial toxins, promote better blood circulation in the capillaries, and protect the blood vessels; that it would prevent ulcers, improve the appetite, stimulate growth, and prevent infections that cause certain types of chronic arthritis; that it would promote good body form, strong bones, and normal teeth; that it would improve the general

health, prevent serious loss of phosphorus and calcium, prevent premature old age, and develop a healthy skin; and that it would produce better nerve tissues and promote better assimilation;

That the *Multa Vitamin Spheroid Capsules* would be efficacious in the cure, mitigation, treatment, and prevention of loss in body weight, digestive trouble, nerve disorders, weakness, acidity, irritability, deafness, catarrh, pallor, restlessness, starvation, brain disorders, fatigue, anemia, excitability, stupidity, poor teeth and bones, retarded growth, poor appetite, lowered resistance to infections, lack of vitality, respiratory troubles, sinus troubles, intestinal disorders, kidney ailments, skin troubles, frequent colds, weakened adrenal gland functioning, muscular weakness and fatigue, drying up of tissues, general weakness, poor nutrition, sterility, convulsions, poor glandular functioning, paralysis, lack of child growth, lack of appetite, neuritis and other nerve ailments, heart disturbances, constipation, too fast development of thyroid, pituitary, and gonad glands, painful joints, tiredness, defective teeth, poor knitting of bones, headaches, poor resistance to infections, weakened blood capillaries, digestive troubles leading to gastric ulcers, weakened functioning of mammary glands, swollen limbs, hemorrhages, adrenal gland dysfunctioning, brittle and soft bones, bow legs, low or high blood calcium, poor assimilation of calcium and phosphorus, lack of muscle tone, disintegration of teeth, deterioration of the blood vessels, lack of vigor, enlarged joints, bone infections, curvature of the spine, impotence, loss of ambition, gradual lack of muscular functioning, degenerative diseases of the nervous system, poor functioning of the mammary and adrenal glands, poor cell respiration, paralysis of the intestines, nervous breakdown, cataracts, loss of hair, skin troubles, lowered general tone, mouth soreness, nausea, urinary pigmentation, skin disease, vomiting, insanity, and tongue redness; that the article would cleanse and alkalinize the body, keep calcium from hardening around the joints and in the arteries, promote growth, and maintain resistance to infections; that it would promote normal glandular functioning, especially for the adrenal gland; that it would lengthen the life span and tone up the entire body; that it would maintain in good condition the membranes of the eyes and the membranes of the digestive tract and urinary tract; that it would keep the skin in good condition, stimulate the appetite and assimilation, promote normal nerve functioning, and destroy acids caused by tiredness; that it would promote normal glandular functioning, especially of the reproductive, adrenal, pituitary, and thymus glands; that it would promote the growth of good teeth, destroy bacterial toxins, promote better blood circulation in the capillaries, and protect the blood vessels; that it would prevent ulcers, improve the appetite, and stimulate growth; that it would prevent infections which cause certain types of chronic arthritis, promote good body form, strong bones, and normal teeth, and prevent serious loss of phosphorus and calcium; that it would prevent miscarriages, improve general health, prevent premature old age, and develop a healthy skin; and that it would produce better nerve tissues, promote better assimilation, and maintain normal functioning of the gastrointestinal tract and the skin;

That the *20-to-1 Liver Concentrate with Iron Capsules* would be efficacious in the cure, mitigation, treatment, and prevention of brooding, sleeplessness, pallid complexion, irritability, neurasthenia, starvation, confusion of mind, lack of elasticity, nerve collapse, weak respiration of the tissues, growth below normal, poor functioning of mammary glands, poor cell respiration, lack of vigor, weight loss, paralysis of the intestines, nervous breakdown, cataracts, loss of hair, skin trouble, lowered general tone, nerve disturbances, mouth soreness,

nausea, urinary pigmentation, constipation, skin disease, vomiting, insanity, and tongue redness; that the article would insure a healthy complexion, give vitality, warmth, magnetism, creative power, and mental endurance, and enable the fibers of the brain to connect and to coordinate thoughts; that it would adapt the nervous system to darkness, improve general health, promote growth, prevent premature old age, lengthen the life span, and develop a healthy skin; that it would produce better nerve tissues and promote better assimilation; and that it would promote general health and maintain normal functioning of the gastrointestinal tract and the skin;

That the *High Potency Vitamin C Tablets* would be efficacious in the cure, mitigation, treatment, and prevention of painful joints, tiredness, defective teeth, poor knitting of bones, headaches, poor resistance to infections, weakened blood capillaries, restlessness, digestive troubles leading to gastric ulcers, weakened functioning of mammary glands, swollen limbs, hemorrhages, paralysis, sterility, and adrenal gland dysfunctioning; that the article would promote growth of good teeth, destroy bacterial toxins, promote better blood circulation in the capillaries, and protect the blood vessels; that it would prevent ulcers, improve the appetite, and stimulate growth; and that it would prevent infections which cause certain types of chronic arthritis;

That the *Russian Radish and Parsley Concentrates Tablets* would be efficacious in the cure, mitigation, treatment, and prevention of loss of body weight, digestive troubles, nerve disorders, weakness, acidity, irritability, deafness, catarrh, pallor, restlessness, starvation, depression, constipation, irregular heart beat, poor muscular coordination, liver trouble, poor digestion, bloating, painful joints, fear, albuminuria, and poor water retention; that the article would cleanse and alkalinize the body and keep calcium from hardening around the joints in the arteries; that it would heal injuries, reduce pain, and balance the body and brain; and that it would keep the proportions of the body and maintain normal heart action.

DISPOSITION: July 13, 1949. Pleas of nolo contendere having been entered, the court imposed a fine of \$2,250 against the corporation, suspended sentence against the individual, and placed him on probation for 2 years.

2866. Misbranding of Retisol Compound. U. S. v. 11 Bottles * * *. (F. D. C. No. 26660. Sample No. 51266-K.)

LABEL FILED: March 21, 1949, Eastern District of Kentucky.

ALLEGED SHIPMENT: On or about February 1 and March 2, 1949, from Cincinnati, Ohio.

PRODUCT: 11 12-ounce bottles of *Retisol Compound* at Covington, Ky., in the possession of the King Drug Co., Store #8. There were on display in the store 4 copies of a newspaper advertisement, clipped from a Cincinnati newspaper by employees of the store. One copy was pasted on each of the two front windows and one on each of the two cash registers in the store.

LABEL, IN PART: "Retisol Compound An efficient alkaline compound containing: Sodium salicylate, sodium citrate, potassium acetate, and hexamethylene."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the newspaper advertisement were false and misleading since the article was not effective in the treatment of the following conditions, stated and implied: "Rheumatic Sufferers Arthritic Sufferers Throw Away Your Canes! Retisol is Here * * * Learn how Retisol has helped people like you, people who have spent torturous days and nights nursing your inflamed bodies of fiery red,

swollen joints, and those sharp stabbing pains that shatter your nerves and keep you awake nights. Your kidneys and bladder will be happy ridding you of the poisonous acids and wastes that have been crippling you. * * * Don't suffer another minute without trying Retisol." The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 3, 1949. Default decree of destruction.

2867. Misbranding of Dr. Shokunbi's Tree of Life F-218. U. S. v. 11 Bottles, etc. (F. D. C. No. 27164. Sample No. 62025-K.)

LIBEL FILED: April 22, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: By the African Herb & Chemical Co., from Memphis, Tenn. The product was shipped on or about March 3, 1949, and a number of circulars were shipped on or about March 8, 1949.

PRODUCT: 11 12-ounce bottles of *Dr. Shokunbi's Tree of Life F-218* at St. Louis, Mo., together with 24 circulars entitled "Why Use Chemical Drugs?"

LABEL, IN PART: "Dr. Shokunbi's Tree of Life F-218 * * * Net Contents 12 Fluid Oz. Yellow Dock, Burdock Root, Poke Root, Buchu Leaves, Peppermint Leaves, May Apple, Juniper Berries, Black Snake Root, Samson Root, Wild Plum Bark, Wild Cherry, Skull Cap, Fever Few, Lady Slipper, Senna, Figs."

NATURE OF CHARGE: Misbranding, Section 502 (a), The label designation "Tree of Life" and the following statements on the label and in the circular were false and misleading since the article was not effective for the purposes stated and implied and was not effective in the treatment of the following diseases and conditions mentioned: (Bottle label) " * * * Indicated for the relief of such ailments as High Blood or Low Blood Pressure, Kidney and Bladder, Rheumatic Pain, Gas on Stomach, Nervousness, Coughs Due to Cold, Chronic Bronchitis, Asthma, Arthritis, Backache" and (circular entitled "Why Use Chemical Drugs?") " * * * if you are suffering from high blood pressure, kidney and bladder, rheumatic pain, gas on stomach, nervousness, coughs due to colds, then you too can get quick relief with the use of the Tree of Life F-218 General Tonic * * * Dr. Shokunbi's F-218 General Tonic for Men and Women * * * The Tree of Life for the Healing of the Nations. * * * Bring your sick and diseased body, mind and spirit to the Tree of Life, planted for the healing of the Nations * * * S. P. Shokunbi * * * has found the leaf thereof, for medicine for the healing of the Nation. * * * if you are suffering with high blood or low blood pressure, rheumatism, kidney and bladder, nervousness, gas on stomach, run down condition, change of life, lumbago, arthritis, etc., then you too should get your bottle today and be convinced."

DISPOSITION: May 18, 1949. Default decree of condemnation and destruction.

2868. Misbranding of Magnetic Ray (device). U. S. v. 2 Boxes * * *. (F. D. C. No. 27022. Sample Nos. 1436-K, 1437-K.)

LIBEL FILED: On or about April 25, 1949, Middle District of North Carolina.

ALLEGED SHIPMENT: On or about March 26, 1949, by the Magnetic Ray Co., from Dallas, Tex.

PRODUCT: 2 boxes each containing a device known as *Magnetic Ray* at Durham, N. C., together with circulars entitled "Magnetic Ray Treatment" and "Directions for taking Magnetic Ray Treatments."

The device consisted essentially of a coil of wire enclosed in a covering of imitation leather and made in the form of a belt. Attached to the device was an electric cord which was to be plugged into an ordinary lighting current outlet.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars accompanying the device were false and misleading since the article was not effective in the treatment of the conditions stated and implied. The statements represented and suggested that the device would be effective in the treatment of arthritis, asthma, anemia, bronchitis, bladder trouble, Bright's disease, colds, catarrhal deafness, catarrh, constipation, diabetes, eczema, epilepsy, goiter, headaches, hemorrhoids, heart diseases, high blood pressure, indigestion, insomnia, impotency, low blood pressure, lumbago, painful menstruation, neuralgia, neuritis, nervous troubles, obesity, paralysis, rheumatism, sciatica, tumors, tuberculosis, varicose veins, ulcers, and sinus trouble; that the device would increase the elimination of poisons, greatly assisting in the removal of toxic conditions; that it would promote and equalize circulation of the blood, relieving congestion in every part of the body; that it would be effective in the relief of pain and other distressing physical sensations; that it would produce marked relaxation and promote sound and refreshing sleep; that it would stimulate a normal functioning of the various glands and other organs of the body; that it would overcome fatigue, which is a usual result of toxemia; that it would increase efficiency, both physical and mental; that it would exert a revitalizing influence upon the sexual or procreative glands; and that it would clear the complexion.

DISPOSITION: May 30, 1949. Default decree of condemnation and destruction.

2869. Misbranding of Sun Kraft Ultra-Violet Ray Lamp. U. S. v. 2,733 Devices
* * *. (F. D. C. No. 26596. Sample No. 41302-K.)

LIBEL FILED: February 18, 1949, Western District of Washington.

ALLEGED SHIPMENT: By Sun-Kraft, Inc., from Chicago, Ill. The devices were shipped on or about April 2, 1947, together with a number of booklets; a number of placards were shipped on or about April 15, 1947.

PRODUCT: 2,733 *Sun Kraft Ultra-Violet Ray Lamps* at Seattle, Wash., in possession of Puget Sound Appliance Sales Co., Inc., together with a number of booklets entitled "How to Use Your Sun-Kraft" and placards entitled "Sun-Kraft Quartz Ultra Violet Ray Therapeutic Lamp \$64.50 Complete." In addition, a number of leaflets entitled "Special Factory Purchase," which the consignee had had printed locally, were in the consignee's possession.

Examination showed that the device consisted of a cold quartz type lamp mounted on a metallic base, and equipped with a timing mechanism. This type of lamp would emit ultraviolet radiations.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the device were false and misleading since the device was not a so-called sun lamp and was not effective in the treatment of the following conditions, stated and implied: (On device) "Sun-Kraft"; (in booklet) "Ultraviolet rays are useful in the treatment of many conditions. * * * Sun-Kraft * * * For any condition not mentioned here * * * For many skin conditions. * * * Acne, psoriasis, many varieties of eczema, scalp conditions and skin tuberculosis * * * For skin ulcers and slow healing wounds. Physicians have found that ulcers and wounds that fail to heal be-

cause of superimposed infection * * * For reducing bacteria content of air"; (on display placard) "* * * Great aid in relieving respiratory conditions." The device was misbranded in the above respect when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), the statements in the leaflets, "Sun-Kraft * * * Helps clear up skin diseases * * * Benefits cold and asthma sufferers Kills bacteria," were false and misleading since the device was not effective in the treatment of the conditions, stated and implied. The device was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: September 26, 1949. Puget Sound Appliance Sales Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the product was ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

2870. Misbranding of Dr. Macdonald's Vy-Tab-O-Lator for Swine (or for Beef Cattle, for Dairy Cattle, for Calves, or for Sheep), and Dr. Macdonald's Vy-Tab-O-Lator Egg Maker Mash. U. S. v. Dr. Macdonald's Vitamized Feed Co. and John R. Macdonald. Pleas of nolo contendere. Fine of \$450 against company and \$150 against individual, together with costs. (F. D. C. No. 25604. Sample Nos. 24961-K to 24966-K, incl.)

INFORMATION FILED: June 2, 1949, Northern District of Iowa, against Dr. Macdonald's Vitamized Feed Co., a corporation, Fort Dodge, Iowa, and John R. Macdonald, president of the corporation.

ALLEGED SHIPMENT: On or about March 11 and 26 and April 5, 1948, from the State of Iowa into the State of Minnesota.

PRODUCT: Analyses disclosed that *Dr. Macdonald's Vy-Tab-O-Lator for swine* consisted chiefly of limestone, charcoal, and salt, together with plant material, sulfur, copper sulfate, iron sulfate, potassium iodide, and other mineral compounds, and containing 19.3 percent of salt, 17.2 percent of calcium, 3.76 percent of phosphorus, .055 percent of iodine, and .090 milligram of niacin per ounce; that *Dr. Macdonald's Vy-Tab-O-Lator for Beef Cattle* consisted chiefly of limestone, salt, charcoal, and sulfur, together with plant material, copper sulfate, iron sulfate, potassium iodide, and other mineral compounds, and containing 20.1 percent of salt, 18.7 percent of calcium, 3.6 percent of phosphorus, and .071 percent of iodine; that *Dr. Macdonald's Vy-Tab-O-Lator for Dairy Cattle* consisted chiefly of limestone, charcoal, salt, and sulfur, together with plant material, copper sulfate, iron sulfate, potassium iodide, and other mineral compounds, and containing 20.4 percent of salt, 20.2 percent of calcium, 4.39 percent of phosphorus, .072 percent of iodine, and 4.2 percent of protein; that *Dr. Macdonald's Vy-Tab-O-Lator for Calves* consisted chiefly of limestone, salt, charcoal, and sulfur, together with plant material, copper sulfate, iron sulfate, potassium iodide, and other mineral compounds, and containing 17.8 percent of salt, 19.5 percent of calcium, 3.6 percent of phosphorus, and .07 percent of iodine; that *Dr. Macdonald's Vy-Tab-O-Lator Egg Maker Mash* consisted chiefly of limestone, salt, and charcoal, together with plant material, copper sulfate, iron sulfate, potassium iodide, and other mineral compounds, and containing 18.6 percent of salt, 19.5 percent of calcium, 2.75 percent of phosphorus, and .076 percent of iodine; and that *Dr. Macdonald's Vy-Tab-O-*

Lator for Sheep consisted chiefly of limestone, salt, charcoal, and sulfur, together with plant material, copper sulfate, iron sulfate, potassium iodide, and other mineral compounds, and containing 18.9 percent of salt, 19.3 percent of calcium, 3.30 percent of phosphorus, and .079 percent of iodine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles, which labeling included accompanying circulars entitled, "Bigger Hog Profits Now Possible," "Dairymen Should Read This Today," "More Feed Dollars From Your Own Grains," "Mix Only 100 lbs. of This Famous Balancer & Conditioner To A Ton of Feed," and "Facts About The Sheep Conditioner Developed By . . . Dr. J. R. Macdonald," were false and misleading since the articles would not be efficacious for the purposes represented and suggested. The statements represented and suggested:

That *Dr. Macdonald's Vy-Tab-O-Lator for Swine* would be efficacious to stimulate glandular organs in the hog and thereby increase the efficiency of the hog's digestive processes; that it would be efficacious as a balancer and conditioner; that it would be efficacious for vigorous health and reproduction and would prevent unthrifty pigs and scours; that it would be efficacious in maintaining health in hogs, in bringing pigs back to health, and in the prevention of necro in hogs; and that it would promote better digestion and assimilation in hogs and aid the digestive system to convert valuable feed nutrients;

That *Dr. Macdonald's Vy-Tab-O-Lator for Beef Cattle*, *Dr. Macdonald's Vy-Tab-O-Lator for Dairy Cattle*, *Dr. Macdonald's Vy-Tab-O-Lator for Calves* would be efficacious to clean heifers in a few hours after they freshen; that the articles would be efficacious to stop scouring and bloating and would help improve the general health of cows; that they would aid in producing sturdy calves; that they would help reduce breeding and calving troubles; that they would keep cows eating and thus help build general health; that they would help reduce mastitis troubles; that they would increase the normal flow of intestinal and digestive juices by stimulating the glands and organs of the body; that they would keep cows "on feed," reduce livestock troubles, loss of appetite, and impactions, stiff joints, and lump jaw; that they would be efficacious to improve materially the general condition of the herd, loosen the skin of hide-bound animals, and put a new bloom on rough hair coats and make them glossy; that they would be efficacious to stimulate the glandular organs of the body, so that these organs function to the fullest capacity; that they would aid in digestion and assimilation; that they would be efficacious to stimulate all of the glands and organs to the fullest capacity, thereby producing secretions vital and necessary for efficient digestion, assimilation, and reproduction; and that they would be efficacious to produce healthier livestock;

That *Dr. Macdonald's Vy-Tab-O-Lator Egg Maker Mash* would act as a balancer and conditioner; that its use would result in healthier hens; that it would be efficacious for vigorous growth, health, and reproduction; that it would aid the chick or chicken to more thoroughly digest its food by stimulating the glandular organs of the body, so that they function to the fullest possible capacity; and that it would help reduce mortality and would increase egg production tremendously;

That *Dr. Macdonald's Vy-Tab-O-Lator for Sheep* would stimulate glandular organs in the lamb, resulting in increased digestive efficiency; that its use would result in more vigorous health for sheep; that it would act as a bal-

ancer and conditioner and would be efficacious for vigorous growth, health, and reproduction; that it would help produce stronger lambs and help reduce losses from disease; and that it would stop scours in lambs and would cut death losses due to parasites and disease to a minimum.

DISPOSITION: July 20, 1949. Pleas of nolo contendere having been entered, the court imposed a fine of \$450 against the corporation and a fine of \$150 against the individual, together with costs.

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¹ (2856) Temporary injunction issued.

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N. J. No.

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2854

¹ (2856) Temporary injunction issued.

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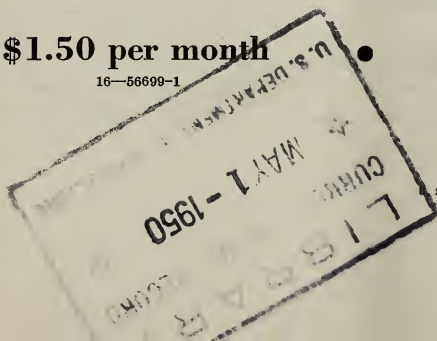
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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2871-2890

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 13, 1950.*

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**DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE
DIRECTIONS OR WARNING STATEMENTS**

2871. Adulteration and misbranding of Neo-Mineral. U. S. v. 13 Cases * * *.
(and 1 other seizure action). (F. D. C. Nos. 27344, 27347. Sample Nos.
47125-K, 51550-K.)

LIBELS FILED: June 21 and 24, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: On or about February 25 and May 21, 1949, by Neo-Mineral Co., Inc., from Detroit, Mich.

PRODUCT: *Neo-Mineral*. 96 3-ounce bottles at Bowling Green, Ohio, and 13 cases, each containing 36 3-ounce bottles, at Youngstown, Ohio. Examination showed that the product was a water solution of ferric sulfate and was contaminated with mold.

LABEL, IN PART: (Bottle) "Neo-Mineral. * * * Take one teaspoonful twice daily, in a full glass of water."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended. Newspaper mats entitled "Sick" and "Health News" had been supplied by the shipper and were used for advertisements appearing in the Youngstown and Bowling Green newspapers.

DISPOSITION: August 1 and 5, 1949. Default decrees of condemnation and destruction.

2872. Misbranding of Vitalic vitamin and mineral tablets and Vitalic calcium and phosphorus tablets with vitamin D. U. S. v. 20 Bottles, etc. (F. D. C. No. 27587. Sample Nos. 55239-K, 55240-K.)

LIBEL FILED: On or about July 28, 1949, Western District of Missouri.

ALLEGED SHIPMENT: On or about June 25, 1949, by Thomas Gaines, from Los Angeles, Calif.

PRODUCT: 20 bottles of *Vitalic vitamin and mineral tablets* and 9 bottles of *Vitalic calcium and phosphorus tablets with vitamin D* at Kansas City, Mo.

LABEL, IN PART: "Vitalic * * * Vitamins and Minerals Vitamins: A, C, D, E, and B-Complex Minerals: Calcium, Iron, Phosphorus 60 Tablets [or "Vitalic Calcium Phosphorus Tablets With Vitamin D Each tablet contains: Dicalcium Phosphate 12½ grs. Vitamin D . . . 250 U. S. P. Units (Irradiated Ergosterol) Contents: 100 Tablets"] * * * Manufactured For and Distributed by Thomas Gaines 458 North Edinburgh Ave., Los Angeles 36, California."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended. The *Vitalic vitamin and mineral tablets* were offered for use in the treatment of cancer, high blood pressure, diabetes, and heart trouble, and to cure and prevent colds, to prevent contagious diseases of childhood, to thin the blood, to keep one young, to rid the body of lice, to stop tooth decay, and to prevent tiredness; the *Vitalic calcium and phosphorus tablets with vitamin D* were offered for use in the treatment of stomach troubles and to prevent tooth decay. The articles were offered for use in such conditions at lectures delivered in Kansas City, Mo., by Thomas Gaines, on or about June 25, 27, 28, and 29, 1949. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 7, 1949. Default decree of destruction.

2873. Misbranding of Sun-O-Ray Ointment. U. S. v. 656 Jars, etc. (F. D. C. No. 27306. Sample No. 51921-K.)

LIBEL FILED: June 8, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: The product was shipped on or about May 11 and 13, 1949, by the Crestline Co., from Chicago, Ill. and a number of circulars were transported by George R. Thurman, from the Crestline Co., on or about May 4, 1949.

PRODUCT: 210 14-ounce jars and 446 4-ounce jars of *Sun-O-Ray Ointment* at Cincinnati, Ohio, in the possession of George R. Thurman, together with a number of circulars entitled "Sun-O-Ray Compound."

The product was offered by Mr. Thurman, during lectures delivered by him at Cincinnati, Ohio, on May 12, 1949, for varicose veins, swollen ankles, stiff knees, and pains of arthritis and swollen joints, conditions for which the product failed to bear any directions for use. Examination showed that the product consisted of a mixture of volatile oils, including safrol, camphor, menthol, and eucalyptol, in a greaseless ointment base.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the circulars were false and misleading since the article was not effective in the treatment of bunions: "Bunions * * * have been eased through brisk massage with Sun-O-Ray Foot Ointment by increasing blood circulation." The article was misbranded in this respect when introduced into, and while in, interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended. The article was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: September 2, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2874. Adulteration of water for injection. U. S. v. 36 Bottles * * *. (F. D. C. No. 27473. Sample No. 27734-K.)

LIBEL FILED: July 18, 1949, Southern District of Illinois.

ALLEGED SHIPMENT: On or about June 28, 1948, from Detroit, Mich.

PRODUCT: 36 100-cc. bottles of *water for injection* at Peoria, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: August 29, 1949. Default decree of condemnation and destruction.

2875. Adulteration of isotonic solution of sodium chloride. U. S. v. 248 Packages
* * *. (F. D. C. No. 27402. Sample No. 51822-K.)

LABEL FILED: June 8, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: On or about January 25, 1949, from Detroit, Mich.

PRODUCT: 248 100-cc. size packages of *isotonic solution of sodium chloride* at Columbus, Ohio.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Isotonic Sodium Chloride Solution," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: August 2, 1949. Default decree of destruction.

2876. Adulteration and misbranding of estrogenic substances. U. S. v. 13 Cartons, etc. (F. D. C. No. 27281. Sample Nos. 19859-K, 19860-K.)

LABEL FILED: May 27, 1949, Middle District of Tennessee.

ALLEGED SHIPMENT: On or about December 5, 1948, and April 5, 1949, by Reed & Carnrick, from Jersey City, N. J.

PRODUCT: 39 cartons, each containing a circular entitled "Estrogenic Substance R&C" and one 20-cc. vial of *estrogenic substances*. Examination showed that the product consisted of a mixture of the natural estrogens, estrone, equilin, and equilenin, normally found in pregnant mares' urine, together with alpha estradiol.

LABEL, IN PART: "Estrogenic Substances (R&C) Solution in Peanut Oil."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity of the article fell below that which it purported to possess since it contained alpha estradiol, which is not a constituent of natural estrogens from pregnant mares' urine, the purported active ingredient of the article.

Misbranding, Section 502 (a), the label statement "Estrogenic Substances * * * Natural Estrogens from pregnant mares' urine was false and misleading as applied to the article, which contained alpha estradiol, an estrogen which does not occur in pregnant mares' urine.

DISPOSITION: July 15, 1949. Reed & Carnrick, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

2877. Adulteration of chorionic gonadotropin. U. S. v. 490 Ampuls * * *.
(F. D. C. No. 26541. Sample No. 21832-K.)

LIBEL FILED: On or about February 24, 1949, Western District of Missouri.

ALLEGED SHIPMENT: On or about December 21, 1948, by Intramed & Co., from New York, N. Y.

PRODUCT: 490 ampuls of *chorionic gonadotropin* at Kansas City, Mo.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since it was for parenteral administration and was unsterile.

DISPOSITION: September 15, 1949. Default decree of destruction.

2878. Adulteration and misbranding of wound dressing. U. S. v. 158 Bottles
* * *. (F. D. C. No. 27183. Sample No. 11192-K.)

LIBEL FILED: May 9, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about April 7, 1949, by Rona Laboratories, Inc., from Carlstadt, N. J.

PRODUCT: 158 bottles of *wound dressing* at New York, N. Y.

LABEL, IN PART: (Bottle) "Clinico's Sterilized Wound Dressing Yellow Petrolatum U. S. P. Gauze 2 in. x 10 yds."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it was a dressing for wounds and was not sterile.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading as applied to a product which was not sterile but which was contaminated with living micro-organisms.

DISPOSITION: July 5, 1949. Default decree of condemnation and destruction.

2879. Adulteration and misbranding of adhesive bandages. U. S. v. 30,000
* * *. (F. D. C. No. 27395. Sample No. 19865-K.)

LIBEL FILED: June 6, 1949, Middle District of Tennessee.

ALLEGED SHIPMENT: On or about April 26, 1949, by the Hampton Mfg. Co., from Carlstadt, N. J.

PRODUCT: 30,000 *adhesive bandages* at Nashville, Tenn.

LABEL, IN PART: "Blue Cross Sterilized * * * Adhesive Strips."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading.

DISPOSITION: July 7, 1949. Default decree of destruction.

2880. Adulteration and misbranding of prophylactics. U. S. v. 60 Gross * * *.
(F. D. C. No. 27555. Sample No. 4739-K.)

LIBEL FILED: July 5, 1949, District of Massachusetts.

ALLEGED SHIPMENT: On or about June 2, 1949, by the Killashun Sales Division, from Akron, Ohio.

PRODUCT: 60 gross of *prophylactics* at Boston, Mass. Examination of samples showed that 6 percent were defective in that they contained holes or were brittle.

LABEL, IN PART: "Silver-Tex Prophylactic Mfd. By The Killian Mfg. Co., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic," "Prophylactics" and "Electronically Tested * * * For Your Protection" were false and misleading as applied to the article, which contained holes and was brittle.

DISPOSITION: August 30, 1949. Default decree of condemnation and destruction.

2881. Adulteration and misbranding of prophylactics. U. S. v. 78 Cartons, etc. (F. D. C. No. 27585. Sample Nos. 63618-K, 63619-K.)

LIBEL FILED: July 19, 1949, Southern District of Florida.

ALLEGED SHIPMENT: On or about February 9 and November 13, 1948, by the Killashun Sales Div., Inc., from Akron, Ohio.

PRODUCT: *Prophylactics*. 78 cartons, each containing 12 packages of 1 dozen and 196 cartons each containing 48 packages of ¼ dozen at Tampa, Fla. Examination of samples indicated that 36.1 percent of the 78-carton lot and 24.3 percent of the 196-carton lot were defective in that they contained holes or were otherwise defective.

LABEL, IN PART: "Texide Prophylactics Mfd. By L. E. Shunk Latex Prod. Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements, "Prophylactic," "Prophylactics," "Electronically Tested," and "For Your Protection," were false and misleading as applied to an article which contained holes or was otherwise defective.

DISPOSITION: September 22, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

2882. Misbranding of Gramer's Sulgly-Minol. U. S. v. 88 Bottles, etc. (F. D. C. No. 27560. Sample Nos. 50471-K, 50472-K.)

LIBEL FILED: July 22, 1949, Eastern District of Washington.

ALLEGED SHIPMENT: By Walter W. Gramer, from Minneapolis, Minn. The product was shipped on or about May 26, 1949, and a number of circulars and leaflets were shipped on or about May 26 and June 7, 1949.

*See also Nos. 2873, 2876, 2878-2881.

PRODUCT: 88 bottles of *Gramer's Sulgly-Minol* at Spokane, Wash., together with a number of leaflets entitled "Walter W. Gramer Co. Manufacturers of Gramer's Sulgly-Minol," "Arthritis * * * Hundreds Claim It's Grip Broken," and "Gramer's Sulgly-Minol Sulphur Solution—Follow These Instructions," and a number of circulars entitled "A Light Should Not Be Hidden—Testimonials."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the leaflets and circulars were false and misleading. These statements represented and suggested that the article was effective as a treatment, cure, and preventative for rheumatism and arthritic conditions and as a treatment for boils and acne, whereas the article was not effective for such purposes.

DISPOSITION: September 15, 1949. Default decree of condemnation and destruction.

2883. Misbranding of Sural. U. S. v. 280 Dozen Cartons, etc. (F. D. C. No. 27565. Sample Nos. 55235-K, 56071-K.)

LABEL FILED: On or about August 3, 1949, Western District of Missouri.

ALLEGED SHIPMENT: On or about April 19 and July 13, 1949, by the Norlon Corp., from New York, N. Y., and New Brunswick, N. J.

PRODUCT: 292 dozen cartons each containing a booklet entitled "Sural" and a 100-tablet bottle of *Sural* at North Kansas City, Mo. Examination showed that each tablet of the product contained aspirin (acetylsalicylic acid) 3.5 grains and calcium succinate 3.25 grains.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the booklet were false and misleading. These statements represented and suggested that the article would be adequate and effective for the treatment and cure of arthritis and rheumatism, whereas it would not be adequate and effective for such purposes.

Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient since the name, which was declared on the label, "acetylsalicylic acid," is not the common or usual name for aspirin.

DISPOSITION: September 15, 1949. Default decree of condemnation and destruction.

2884. Misbranding of Jay's Worm Syrup. U. S. v. 158 Bottles * * *. (F. D. C. No. 27149. Sample No. 3186-K.)

LABEL FILED: May 4, 1949, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about March 9, 1949, by Commerce Drug Co., Inc., from Brooklyn, N. Y.

PRODUCT: 158 2-ounce bottles of *Jay's Worm Syrup* at Richmond, Va.

LABEL, IN PART: "Jay's Worm Syrup Alcohol 2 Per Cent Contains Spigelia, Senna, Oils of Caraway & Anise."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Worm Syrup * * * An effective preparation for the removal of Pin Worms Round Worms" were false and misleading since the article was not effective in the removal of worms.

DISPOSITION: June 21, 1949. Default decree of condemnation and destruction.

2885. **Misbranding of Buff's Purgative Elixir Compound.** U. S. v. 192 Bottles
* * *. (F. D. C. No. 27276. Sample No. 2104-K.)

LIBEL FILED: June 1, 1949, District of Columbia.

ALLEGED SHIPMENT: On or about June 28, 1948, by the Frank Drug Co., from Arlington, Va.

PRODUCT: 192 6-ounce bottles of *Buff's Purgative Elixir Compound* at Washington, D. C. Analysis showed that the product consisted essentially of epsom salt, a laxative plant drug, alcohol, water, and flavoring materials.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the article were false and misleading since the article was not effective in the treatment of the conditions stated and implied: "Aid in the relief of persons afflicted with Dyspepsia, Bilious Attacks, Loss of Appetite and other Digestive Disorders * * * exciting the Digestive Tract to a healthy, normal action."

DISPOSITION: October 19, 1949. Default decree of condemnation. The court ordered that the product be delivered to a local hospital for its use, and not for sale, since the hospital had advised that while they did not care to use the contents, they could use the 192 6-ounce bottles.

2886. **Misbranding of rectal suppositories.** U. S. v. 33 Dozen Boxes * * *.
(F. D. C. No. 27455. Sample No. 55515-K.)

LIBEL FILED: On or about July 14, 1949, Western District of Missouri.

ALLEGED SHIPMENT: On or about March 18 and 25, 1949, by the S. E. Massengill Co., from Bristol, Tenn.—Va.

PRODUCT: 33 dozen boxes of *rectal suppositories* at Kansas City, Mo.

LABEL, IN PART: "Rectal Suppositories Aminophylline and Phenobarbital Sodium."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Rectal Suppositories Aminophylline and Phenobarbital Sodium" was false and misleading since it implied that the article was suitable for the administration of aminophylline and phenobarbital sodium by rectum, whereas it was not suitable for such purpose since it would not melt at body temperature; and the label statement "Suppositories readily fuse or melt when exposed to body temperature" was false and misleading since the article would not fuse or melt at such temperature.

DISPOSITION: September 15, 1949. Default decree of destruction.

2887. **Misbranding of Baldwin Hair and Scalp Tonic.** U. S. v. 8 Bottles, etc.
(F. D. C. No. 27178. Sample No. 46140-K.)

LIBEL FILED: May 9, 1949, Southern District of Illinois.

ALLEGED SHIPMENT: On or about September 22, 1948, by the O. C. Baldwin Products Co., from Burlington, Iowa.

PRODUCT: 8 8-ounce bottles and 37 16-ounce bottles of *Baldwin Hair & Scalp Tonic* and 37 circulars entitled "A New Science in Trichology" and 18 display cards entitled "Baldwin Hair and Scalp Tonic" at Quincy, Ill.

Examination showed that the product consisted essentially of isopropyl alcohol, 78 percent, and boric acid and menthol, and green coloring matter such as chlorophyll.

LABEL, IN PART: "Baldwin Antiseptic Hair and Scalp Tonic * * * Contains 64% Alcohol by Vol. (not Ethyl)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling were false and misleading since the product was not a hair tonic and was not effective for the purposes represented and suggested: (Bottle label) "Hair and Scalp Tonic" and (circular and display card) "Hair and Scalp Tonic * * * Promotes the growth of new hair * * * discourages seborrhea—(dandruff), and falling hair. Tightens up and promotes the growth of already existing hair, restores natural color in most instances"; Section 502 (b) (2), the product was a drug in package form and failed to bear a label containing an accurate statement of the quantity of the contents; and, Section 502 (c), the label failed to reveal the kind and amount of alcohol present.

DISPOSITION: June 6, 1949. Default decree of condemnation and destruction.

2888. Misbranding of Jack Eldredge Foot Roller and Jack Eldredge Shock Absorber. U. S. v. 35 Devices, etc. (F. D. C. No. 26604. Sample Nos. 41695-K, 41697-K.)

LABEL FILED: February 17, 1949, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about February 12, April 28, May 15, and June 6, 1948, by the Jack Eldredge Health Foundation, from Cleveland, Ohio.

PRODUCT: 35 devices known as *Jack Eldredge Foot Roller*, 14 cartons each containing a circular entitled "Something to Think About," and a device known as *Jack Eldredge Shock Absorber* at Milwaukee, Wis., together with 59 additional circulars of the above title. The *Jack Eldredge Foot Roller* consisted of a corrugated wooden roller; the *Jack Eldredge Shock Absorber* consisted of a rubber and leather shoe insole, equipped with pockets, together with assorted sizes of sponge rubber inserts.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling were false and misleading since the devices were not effective in the treatment of the conditions stated and implied: (Statements in circular relating to *Jack Eldredge Foot Roller*) "Something to think about" * * * The following brief and simple instructions will improve the circulation of the blood, which in turn tones up the muscles, removes irritation, and aids the blood stream to feed the muscles and strengthen the 26 bones in each foot * * * feeling caused by blood circulating through congested tissues * * * Arch builder * * * Bunions," (statements on carton relating to *Jack Eldredge Shock Absorber*) "Shock Absorber * * * relief from sore * * * aching feet * * * promotes circulation," (circular) "Stop saying my feet are killing me * * * Shock Absorbers * * * relief from sore * * * aching feet, fallen arches, bunions, calluses, all foot and leg pains, or any kind of foot trouble, through my method of mechanical foot correction * * * Promotes circulation * * * with body twisted and joints all bent. Bunions, hammer toes and corns on feet * * * changing to a more natural postural position * * * promotes proper and better functional activity * * * circulation is to be stimulated * * * foot condition improved * * * we have reports from many of our users that pains in the back, knees, hips, cramps in the legs and even their posture, has

been greatly benefited, by the use of the Jack Eldredge Shock Absorbers * * * nervous system can go haywire * * * Nervousness, pain in hips, leg pains, varicose veins, ingrown toe nail, calluses, tender heel, flat foot, corns, cramped toes, bunions, pain in knee, neuritis and sciatica, backache, body fatigue, droop shoulder * * * marks of pain leave her face * * * pains * * * eliminated * * * I was laid off for 90 days because my feet went back on me * * * Jack Eldredge Shock Absorbers put me back to work in 5 days."

DISPOSITION: July 11, 1949. Default decree of condemnation and destruction.

2889. Misbranding of Therm-Massage Infra-Red Heat Applicator. U. S. v. 22 Cartons * * *. (F. D. C. No. 27301. Sample No. 42753-K.)

LIBEL FILED: June 16, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about March 5, 1947, by Sibert & Co., from Jamaica, L. I., N. Y.

PRODUCT: 22 cartons each containing 1 *Therm-Massage Infra-Red Heat Applicator*, together with a circular bearing the same name at Chicago, Ill. Examination showed that the device consisted of 2 pieces of molded plastic, one serving as the handle and the other containing an electrically heated coil.

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the device bore false and misleading curative and therapeutic claims in substantially the same respect as the device involved in notices of judgment on drugs and devices, No. 2592.

DISPOSITION: September 12, 1949. Default decree of condemnation and destruction.

2890. Misbranding of Vitalizer (device). U. S. v. 1 Vitalizer, etc. (F. D. C. No. 27218. Sample No. 42044-K.)

LIBEL FILED: May 20, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about February 4, 1949, from Milwaukee, Wis., by the Cosmic Wave Machine Co.

PRODUCT: 1 *Vitalizer* (device) at Chicago, Ill., together with a circular entitled "Cosmic Wave Vitalizer" and another entitled "Cosmic Wave Vitalizer Endocrine Dysfunctions." The device was designed to produce an electromagnetic field.

LABEL, IN PART: "Vitalizer Uses 110 to 125 Volts AC."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Vitalizer" and certain statements in the circulars were false and misleading. The name represented and suggested that the device would produce vitality, and statements in the circulars represented and suggested that the device, by application of its waves to the blood passing through the feet, would bring about a response of the nerves and tissues and would materially improve the venous, arterial, and capillary circulation; that it would wash away congestion, relieve pressure and pain, and revitalize atrophied muscles; and that it would be effective in the treatment of malaria fever, prostate trouble, gall bladder sluggishness, nervous indigestion, weak back, nervous and dizzy spells, varicose veins, headaches, colds, fallen arches, phlebitis, leg ulcers, kidney convulsion, backaches, foot trouble, arthritis, asthmatic conditions, blood pressure, burns, and in-

growing toenails. The device would not produce vitality, and it was not effective in the treatment of the conditions, diseases, and symptoms stated and implied.

DISPOSITION: July 28, 1949. Default decree of condemnation and destruction.

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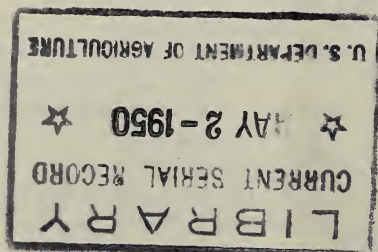
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SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2891-2910

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *March 13, 1950.*

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DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2891. Adulteration and misbranding of vitamin B₁ injection. U. S. v. 804 Vials.
* * *. (F. D. C. No. 27696. Sample No. 7880-K.)

LIBEL FILED: August 18, 1949, Western District of New York.

ALLEGED SHIPMENT: On or about April 15, 1949, by Apco Laboratories, Inc., from Newark, N. J.

PRODUCT: 804 10-cc. vials of *vitamin B₁ injection* at Buffalo, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride Injection" (vitamin B₁), a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use. The article was misbranded in interstate commerce.

DISPOSITION: September 12, 1949. Default decree of condemnation and destruction.

2892. Misbranding of Crest Foot Ointment. U. S. v. 17 Cases * * *.
(F. D. C. No. 27595. Sample Nos. 52021-K, 52022-K.)

LIBEL FILED: July 21, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: On or about June 29 and July 1, 1949, from Huntington, W. Va., and Chicago, Ill.

PRODUCT: 17 cases, each containing 12 14-ounce jars, of *Crest Foot Ointment* at Cleveland, Ohio, in possession of Ben Garber.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, and verbal statements, made by the consignee while offering the article for sale, contained misinformation concerning the article. The article was misbranded in the above respect while held for sale after shipment in interstate commerce.

DISPOSITION: September 7, 1949. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2893. Adulteration of iron sulfate solution. U. S. v. 2 Barrels, etc. (F. D. C. No. 27598. Sample Nos. 1676-K, 1685-K, 1686-K.)

LIBEL FILED: July 28, 1949, Western District of South Carolina.

ALLEGED SHIPMENT: Between the approximate dates of September 20, 1947, and November 15, 1948, from Bay Springs and Louin, Miss.

PRODUCT: 21 50-gallon barrels of *iron sulfate solution* at Union, S. C.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence

of mold. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 1, 1949. Default decree of condemnation and destruction.

2894. Adulteration of mineral salts solution. U. S. v. 1 Barrel * * *
(F. D. C. No. 27434. Sample No. 53494-K.)

LIBEL FILED: June 27, 1949, Middle District of Alabama.

ALLEGED SHIPMENT: On or about February 23, 1949, from Bay Springs, Miss.

PRODUCT: 1 25-gallon barrel of *mineral salts solution* at Montgomery, Ala. Examination showed that the product was a water solution of ferric sulfate and was contaminated with mold.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: July 22, 1949. Default decree of condemnation and destruction.

2895. Adulteration and misbranding of Heintzelman's Famous Swedish Elixir Of Life (Formula No. 1620). U. S. v. 2 Drums, etc. (F. D. C. No. 27844. Sample Nos. 13807-K, 13808-K.)

LIBEL FILED: September 16, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 17, 1948, and June 24, 1949, from New York, N. Y.

PRODUCT: *Heintzelman's Famous Swedish Elixir Of Life (Formula No. 1620)*. 2 drums and 37 retail cartons at Philadelphia, Pa., in possession of Heintzelman's Pharmacy, Inc., together with a number of circulars entitled "Dr. Heintzelman's Famous Swedish Elixir Of Life." The 37 retail cartons were prepared by repacking a portion of the product contained in the drums. Analysis showed that the product in the drums and cartons was a coarsely ground mixture of plant parts, including aloe, agaric, myrrh, gentian, galangal, rhubarb, American saffron, and laurel.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the portion of the article contained in the retail cartons consisted in whole or in part of a filthy substance by reason of the presence of insects. This portion was adulterated while held for sale after shipment in interstate commerce.

Misbranding, Section 502 (a) certain statements in the labeling of the article in the drums and cartons, namely, on the carton label and in the circulars, were false and misleading. The statements represented and suggested that the article was effective in the treatment of bilious and gastric attacks, liver and kidney complaints, dyspepsia, hypochondria, gout, yellow jaundice, headache, and various forms of nervous and rheumatic complaints; that daily use of the article would establish a long and healthy life, invigorate the body and mind, and give relief to all nervous and rheumatic complaints; that it would cleanse the stomach and liver, increase the appetite, promote digestion, and remove all colic and bilious affections; and that it was an effective remedy for worms in children and adults and for hysterical affections of women and women's complaints. The article was not effective in the treatment of the conditions or for the purposes stated and applied. The

article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: October 18, 1949. Default decree of condemnation and destruction.

2896. Adulteration of spikenard root. U. S. v. 2,300 Pounds * * *. (F. D. C. No. 27630. Sample No. 10059-K.)

LABEL FILED: August 4, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about July 7, 1949, by the Wilcox Drug Co., from Boone, N. C.

PRODUCT: 2,300 pounds of *spikenard root* in 6 unlabeled bales at Jersey City, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects and insect-infested material, and of a decomposed substance by reason of the presence of moldy material.

DISPOSITION: September 26, 1949. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2897. Adulteration of water for injection. U. S. v. 38 Vials * * *. (F. D. C. No. 27474. Sample No. 43210-K.)

LABEL FILED: July 19, 1949, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about May 11, 1949, by the Vitamix Corp., from Philadelphia, Pa.

PRODUCT: 38 100-cc. vials of *water for injection* at Detroit, Mich.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: September 13, 1949. Default decree of condemnation and destruction.

2898. Adulteration of isotonic solution of sodium chloride. U. S. v. 90 Vials * * *. (F. D. C. No. 27588. Sample No. 13491-K.)

LABEL FILED: July 19, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about June 16, 1949, from Decatur, Ill., by the Taylor Pharmacal Co.

PRODUCT: 90 100-cc. vials of *isotonic solution of sodium chloride* at Allentown, Pa.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sterile Isotonic Sodium Chloride Solution for

*See also No. 2891.

Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: August 24, 1949. Default decree of condemnation and destruction.

2899. Adulteration of physiological salt solution. U. S. v. 16 Vials * * * .
(F. D. C. No. 27589. Sample No. 56573-K.)

LABEL FILED: July 21, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about May 6, 1949, by the Gotham Pharmaceutical Co., Inc., from Brooklyn, N. Y.

PRODUCT: 16 100-cc. vials of *physiological salt solution* at Passaic, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Physiological Salt Solution for Parenteral Use," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: September 26, 1949. Default decree of condemnation. The product was ordered delivered to the Food and Drug Administration, for experimental purposes.

2900. Adulteration and misbranding of chorionic gonadotropin. U. S. v. 181 Vials * * * . (F. D. C. No. 27616. Sample No. 13532-K.)

LABEL FILED: July 29, 1949, Eastern District of Pennsylvania; libel amended August 24, 1949.

ALLEGED SHIPMENT: On or about June 10, 1949, the Associated Ross-Good Laboratories, Inc., Philadelphia, Pa., received from Brooklyn, N. Y., a returned shipment of 181 labeled and unlabeled vials of *chorionic gonadotropin*. Each of the labeled vials contained either 5,000 International Units or 10,000 International Units of *chorionic gonadotropin*. Examination showed that the product was not sterile and that the labeled vials contained substantially less than the declared amounts of *chorionic gonadotropin*.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since it was for parenteral administration and was not sterile; and the strength of the article in the labeled vials differed from that which it purported to possess.

Misbranding, Section 502 (a), the label statements "5,000 International Units" and "10,000 International Units" were false and misleading as applied to the labeled portion of the article, the potency of which was less than that it purported to possess.

DISPOSITION: September 26, 1949. Default decree of condemnation and destruction.

2901. Adulteration of aminophylline injection and thiamine hydrochloride injection. U. S. v. 51 Ampuls, etc. (F. D. C. No. 27591. Sample Nos. 56746-K, 56747-K.)

LABEL FILED: July 21, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about January 3 and June 1, 1949, from Brooklyn, N. Y.

PRODUCT: 51 10-cc. ampuls of *aminophylline injection* and 222 10-cc. vials of *thiamine hydrochloride injection* at Hoboken, N. J.

NATURE OF CHARGE: Misbranding, Section 501 (b), the ampuls of the *aminophylline injection* and the vials of the *thiamine hydrochloride injection* purported to be and were represented as "Aminophylline Injection" and "Thiamine Hydrochloride Injection," respectively, drugs the names of which are recognized in the United States Pharmacopoeia, an official compendium, and their quality and purity fell below the official standards since they were contaminated with undissolved material. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 26, 1949. Default decree of condemnation. The products were ordered delivered to the Food and Drug Administration, for experimental purposes.

2902. Adulteration of thiamine hydrochloride injection. U. S. v. 16 Vials * * *.
(F. D. C. No. 27684. Sample No. 60841-K.)

LABEL FILED: August 8, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about April 28, 1949, from Los Angeles, Calif.

PRODUCT: 16 30-cc. vials of *thiamine hydrochloride injection* at St. Louis, Mo.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Thiamine Hydrochloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: September 8, 1949. Default decree of condemnation and destruction.

2903. Adulteration and misbranding of absorbent cotton. U. S. v. 551 Packages * * *.
(F. D. C. No. 27680. Sample No. 49536-K.)

LABEL FILED: August 5, 1949, District of Colorado.

ALLEGED SHIPMENT: On or about January 14, 1947, by Supreme First Aid Co., Inc., from New York, N. Y.

PRODUCT: 551 ½-ounce packages of *absorbent cotton* at Denver, Colo.

LABEL, IN PART: "Real Aid Sterilized U. S. P. Absorbent Cotton."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (a), the label statement "Sterilized U. S. P." was false and misleading as applied to an article which was not sterile.

DISPOSITION: September 8, 1949. Default decree of condemnation and destruction.

2904. Adulteration and misbranding of bandages. U. S. v. 54 Packages * * *.
(F. D. C. No. 27463. Sample No. 60814-K.)

LIBEL FILED: July 11, 1949, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about April 27 and May 16, 1949, by Surgical Dressings, Inc., from Boston, Mass.

PRODUCT: 54 packages of *bandages* at St. Louis, Mo.

LABEL, IN PART: "Sterilastic First Aid Bandage."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity or quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "Sterilastic * * * may be used in an emergency" were false and misleading as applied to an article which was not sterile but which was contaminated with living micro-organisms.

DISPOSITION: August 15, 1949. Default decree of condemnation and destruction.

2905. Adulteration and misbranding of adhesive bandages. U. S. v. 2,800 Packages * * *. (F. D. C. No. 27394. Sample No. 51778-K.)

LIBEL FILED: June 3, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: On or about April 25, 1949, by the Hampton Mfg. Co., from Carlstadt, N. J.

PRODUCT: 2,800 packages of *adhesive bandages* at Cincinnati, Ohio.

LABEL, IN PART: "Blue Cross * * * Sterilized 6 Adhesive Bandages."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was not sterile but was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statement "Sterilized" was false and misleading.

DISPOSITION: September 2, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

2906. Misbranding of Polson Formula AR-No. 1 and JM3 Sulphur Solution. U. S. v. 183 Bottles, etc. (F. D. C. No. 27007. Sample Nos. 41915-K, 41916-K.)

LIBEL FILED: April 29, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about December 30, 1948, and March 7, 1949, from Los Angeles, Calif., and Long Beach, N. Y.

PRODUCT: 183 bottles of *Polson Formula AR-No. 1* and 65 bottles of *JM3 Sulphur Solution* at Chicago, Ill., together with a number of circulars entitled "Relief from Aches and Pains." The circulars were printed locally on in-

* See also Nos. 2895, 2900, 2903-2905.

structions of Polson's Health Food Store at Chicago, Ill., and were on display in the store with the products.

LABEL, IN PART: "Polson Formula AR-No. 1. Net Contents: 300 Tablets Six Tablets Contain: Vitamin C (Ascorbic Acid) 1200 U. S. P. Units Vitamin D (from Activated Ergosterol) 800 U. S. P. Units," and "JM3 Sulphur Solution Active Ingredients Potassium Polysulphide 3.25% Potassium Thiosulphate 1.50% Sodium Polysulphide 3.25% Sodium Thiosulphate 1.50% Inert Ingredients 90.50% Contents 8 Fl. Oz."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading since they represented and suggested that the articles were an adequate and effective treatment for rheumatism, arthritis, neuritis, and sciatica, and that they were effective in the relief of pain from such conditions and diseases, whereas the articles were not an adequate and effective treatment for, and were not effective in the relief of pain from, such conditions and diseases. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: August 25, 1949. Polson's Health Foods, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the products were ordered released under bond for the purpose of relabeling the *Polson Formula AR-No. 1* and destroying the *JM3 Sulphur Solution* and the circulars, under the supervision of the Federal Security Agency.

2907. Misbranding of Kloronol. U. S. v. 27 Bottles * * *. (F. D. C. No. 27798. Sample No. 46308-K.)

LABEL FILED: September 1, 1949, Southern District of Illinois.

ALLEGED SHIPMENT: On or about June 30, 1949, by the Sumlar Co., from Brooklyn, N. Y.

PRODUCT: 27 1-ounce bottles of *Kloronol* at Peoria, Ill.

LABEL, IN PART: "Kloronol * * * Contains: * * * ephedrine sulfate, epinephrine hydrochloride, potassium bicarbonate, borax, thymol, eucalyptol, and methyl salicylate."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in labeling accompanying the article were false and misleading since they represented and suggested that the article was an adequate and effective treatment for sinusitis, catarrh, hay fever, sinus headaches, and earaches, whereas the article was not an adequate and effective treatment for such conditions: (Letter) "We are pleased to acknowledge your order for the following which we have shipped you per invoice enclosed: 3 dozen Kloronol Sinus Remedy. We are sending you herewith also new advertising schedules," (advertising insertion order) "Please publish advertising of Kloronol Sinus Remedy * * * Kloronol Ad No. 214 'Sinus' * * * Kloronol Ad No. 215 'Hay Fever' * * * Use 'Hay Fever' mat herewith," and (advertising mat and proof sheet of an advertisement) "Hay Fever Sinus Victims Find Curb For Misery Due To Nasal Congestion * * * Relief at last from torture of sinus, catarrh, and hay fever due to nasal congestion * * * Men and women with agonizing sinus headaches, clogged nostrils, earache, hawking and sneezing misery tell of blessed relief after using it. Kloronol Costs \$3.00, but considering results, this is not expensive."

DISPOSITION: October 11, 1949. Default decree of condemnation and destruction.

2908. Misbranding of Calgum. U. S. v. 19 Boxes * * *. (F. D. C. No. 27196. Sample No. 55506-K.)

LIBEL FILED: On or about May 19, 1949, Western District of Missouri.

ALLEGED SHIPMENT: On or about February 4, 1949, by the Calgum Co., from Topeka, Kans.

PRODUCT: 19 boxes of *Calgum* at Kansas City, Mo. Examination showed that the product was a chewing gum, containing small amounts of calcium, phosphorus, and fluorine.

LABEL, IN PART: "Calgum Nourishes Bones and Teeth."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article was effective to prevent and correct degeneration of body, bones, and nerves, caries, soft teeth, brittle nails, malnutrition, nervousness, loss of weight, and lowered resistance, whereas the article was not effective for such purposes.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: September 15, 1949. Default decree of condemnation and destruction.

2909. Misbranding of Super Polar Ray (device). U. S. v. 20 Devices, etc. (F. D. C. No. 27329. Sample No. 51928-K.)

LIBEL FILED: June 15, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: In the year 1931, from Homer City, Pa.

PRODUCT: 20 devices known as *Super Polar Ray*, together with 17 coils of wire and a number of circulars entitled "Facts You Should Investigate" and "Revitalize Revive Rebuild," in the possession of Mrs. Alma H. Minning, Cincinnati, Ohio. Examination showed that the device consisted of a series of coils of wire in a leatherette covering, with a short length of wire for plugging into an electrical socket and additional coils consisting of 56 turns of covered copper wire for use in repairing the device.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading. These statements represented and suggested that the device would be effective in the treatment of arthritis, asthma, bladder trouble, Bright's disease, bronchitis, "colytus," constipation, diabetes, eczema, gastritis, goiter, heart trouble, hemorrhoids, high blood pressure, low blood pressure, indigestion, insomnia, lumbago, nervous disorders, neuralgia, neuritis, pernicious anemia, "polytus," poor circulation, "prostrate" trouble, rheumatism, sciatica, sinus trouble, ulcerated stomach, "varicos" veins, eye trouble, and cancer of the stomach. The device would not be effective in the treatment of these conditions. The device was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 23, 1949. Default decree of condemnation. A number of the devices and circulars were ordered delivered to the Food and Drug Administration, and the remainder were ordered destroyed.

**2910. Misbranding of Therm-Massage Infra-Red Heat Applicator. U. S. v. 636
Cartons, etc. (F. D. C. No. 27259. Sample No. 60305-K.)**

LIBEL FILED: May 25, 1949, Eastern District of Michigan.

ALLEGED SHIPMENT: By Sibert & Co., from Newark, N. J. The device was shipped on or about December 3 and 8, 1948, and quantities of printed matter were shipped during the later part of 1948.

PRODUCT: 636 cartons each containing 1 *Therm-Massage Infra-Red Heat Applicator* at Dearborn, Mich., together with a number of display sheets entitled "Infra-Red Therm-Massage Heat Applicator," "Heat Massage Those Pains Away," and "Infra-Red Electric Heat Applicator," and a number of display cards entitled "Therm-Massage." The cartons containing the device were labeled with three different type labels, two of which contained the name of the manufacturer, Sibert & Co., and the third, pasted on by the consignee, contained the name of the distributor, the Ideal Sales Co.

Examination of the device showed that it consisted of two pieces of molded plastic, one serving as the handle and the other containing an electrically heated coil.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on some of the cartons containing the device, on the display sheets, and on the display cards, were false and misleading. These statements represented and suggested that the device would be efficacious in the cure, mitigation, and treatment of colds, sinus, rheumatic pains, muscular aches and pains, stiff neck, sore throat, pains in the back, sprains, bruises, leg cramps, headache, arthritis, aching joints, neuralgia, rheumatism, neuritis, aching muscles, foot cramps, head pains, and back sprains, and that the device would help to prevent wrinkles and eliminate muddy complexion and skin blemishes. The device would not fulfill the promises of benefit stated and implied. The device was misbranded in the above respects when introduced into and while in interstate commerce.

Further misbranding, Section 502 (a), certain statements on the cartons which had been relabeled, namely, "Colds - Sinus Rheumatic Pains Muscular Aches & Pains Stiff Neck - Sore Throat Pains in Back," were false and misleading since the device would not fulfill the promises of benefit stated and implied. The device was misbranded in this respect while held for sale after shipment in interstate commerce.

DISPOSITION: September 26, 1949. The Ideal Sales Co., Dearborn, Mich., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the devices were ordered released under bond for relabeling, under the supervision of the Federal Security Agency.

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SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N. J. No.		N. J. No.
Apco Laboratories, Inc.:		Minning, Mrs. A. H.:	
vitamin B ₁ -----	2891	Super Polar Ray (device)----	2909
Associated Ross-Good Labora- tories, Inc.:		Polson's Health Food Store:	
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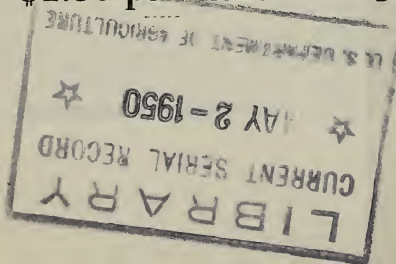
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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2911-2930

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

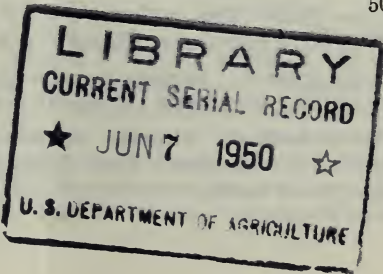
PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., May 4, 1950.

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 2912, 2929; failure to bear a label containing an accurate statement of the quantity of the contents, No. 2912; labeling information not likely to be understood by the ordinary individual under customary conditions of purchase and use, No. 2916.



DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2911. Misbranding of Nue-Ovo. U. S. v. 516 Cases * * *. Tried to the court. Verdict for the Government. Decree of condemnation and destruction. (F. D. C. No. 23385. Sample No. 70859-H.)

LIBEL FILED: July 30, 1947, Southern District of California.

ALLEGED SHIPMENT: On or about March 18 and April 2 and 23, 1947, by Research Laboratories, Inc., from Portland, Oreg.

PRODUCT: 516 cases, each containing 18 1-pint bottles, of *Nue-Ovo* at Los Angeles, Calif.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the only directions appearing in the labeling, namely, "Directions for use of Nue-Ovo For Adults and Children over 10 Years of Age: Take (1) tablespoonful undiluted immediately before each meal and four (4) tablespoonfuls just before retiring. For Children 7 to 10 Years of Age: One-half of adult dose. Do not give to children under 7 years except on the advice of a physician. Shake Well Before Using," were inadequate in that the directions failed to reveal the diseases or conditions of the body for which the article when used as directed would be effective.

DISPOSITION: March 1, 1948. Research Laboratories, Inc., filed an answer denying that the product was misbranded and alleging as an affirmative defense that the Research Laboratories, Inc., was the owner of the product and was holding it in storage at a warehouse at Los Angeles, Calif.; that the product was to be labeled or repacked in substantial quantities at an establishment other than where it was originally processed; and that the Research Laboratories, Inc., was the operator of the establishment where the article was to be labeled or repacked.

The case came on for trial before the court without a jury on April 27, 1948, and was concluded on the same day with a verdict for the Government. On May 13, 1948, findings of fact and conclusions of law were filed in accordance with such verdict, and judgment was entered providing for condemnation and destruction of the product. On July 2, 1948, a stay of execution was granted pending final disposition by the United States Supreme Court of the petition for certiorari, which had been filed in the case reported in notices of judgment No. 2921. Following denial of certiorari, action was taken in regard to the execution of the judgment of May 13, 1948, resulting in the destruction of the product on January 19, 1949.

2912. Misbranding of nembutal capsules. U. S. v. Katz Drug Co. Plea of nolo contendere. Fine, \$375. (F. D. C. No. 25609. Sample Nos. 68535-H to 68539-H, incl., 21167-K, 21168-K, 21175-K, 21176-K, 21182-K, 21184-K, 21185-K.)

INFORMATION FILED: June 28, 1949, Western District of Missouri, against the Katz Drug Co., a corporation, Kansas City, Mo.

INTERSTATE SHIPMENT: Between the approximate dates of September 15 and October 22, 1947, from North Chicago, Ill., of quantities of *nembutal capsules*.

LABEL, WHEN SHIPPED: "Capsules Nembutal Pentobarbital Sodium * * * 1½ grs. * * * Caution: To be dispensed only by or on the prescription of a physician or dentist."

ALLEGED VIOLATION: Between February 11 and March 26, 1948, while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of capsules of the drug to be repacked into bottles and to be sold to various persons without a prescription, which acts of the defendant resulted in the capsules being misbranded. The repackaged capsules were labeled "Katz Drug Co * * * Kansas City, Missouri No. 317745 Dr. McCracken One at bed time for sleep if needed."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drug failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the label failed to bear the common or usual name of the drug, "pentobarbital sodium"; Section 502 (d), the repackaged drug was for use by man and contained a chemical derivative of barbituric acid, which derivative had been found, by the Administrator of the Federal Security Agency, after investigation, to be and by regulations designated as habit forming, and the label failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith, the statement "Warning—May be habit forming"; and, Section 502 (f) (1), the labeling of the repackaged drug failed to bear adequate directions for use since the directions for use on the labeling "One at bed time for sleep if needed" were not adequate directions.

DISPOSITION: November 7, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$375.

2913. Misbranding of Fruitonya, Neutraton, Hematon No. 1, Hematon No. 2, Phospho B Complex, Ribo Ton, and Java Ton. U. S. v. 144 Bottles, etc. (F. D. C. No. 24730. Sample Nos. 2029-K, 2030-K, 2032-K to 2036-K, incl.)

LIBEL FILED: April 15, 1948, District of Columbia; libel amended October 12, 1948.

ALLEGED SHIPMENT: By the Miracle Food Co., from Philadelphia, Pa.

PRODUCT: 144 1-quart bottles of *Fruitonya*; 24 13-ounce cans of *Neutraton*; 24 16-ounce bottles of *Hematon No. 1*; 24 75-tablet boxes of *Hematon No. 2*; 24 50-capsule boxes of *Phospho B Complex*; 24 100-tablet boxes of *Ribo Ton*; and 24 4-ounce cans of *Java Ton* at Washington, D. C.

The products were advertised for various diseases, symptoms, and conditions at lectures given by J. D. Levine at Washington, D. C., on April 5, 6, and 12, 1948.

LABEL, IN PART: "Fruitonya * * * Contains invert sugar, True fruit extracts, Reinforced with Natural flavors & fruit acids"; "Neutraton * * * Contains Lactose, Skimmed Milk, Dicalcium phosphate, Irradiated Milk, Whey Powder"; "Hematon No. 1 * * * Three teaspoonfuls provide: Vitamin A . . . 5,000 U. S. P. Units, Vitamin D . . . 1,200 U. S. P. Units, Vitamin B₁ (Thiamin) . . . 1 mg., Vitamin B₂ (G) (Riboflavin) . . . ½ mg., Niacinamide . . . 10 mg., Green Iron & Ammon. Citrate . . . 3 grs., Iron . . . 30 mgs."; "Hematon No. 2 * * * Each tablet Contains: 2,500 U. S. P. Units Vitamin A, 250 U. S. P. Units Vitamin D, ½ Mgm. Colloidal Copper, 5 Mgm. Iron"; "Phospho B Complex * * * Contains: Vitamin B₁ (Thiamin Chloride) 500 U. S. P. Units, Vitamin B₂ (Riboflavin) 2,000 Micrograms, Vitamin B₆ (Pyridoxine) 30 Micrograms, Calcium Pantothenate 250 Micrograms, Niacin Amide 10,000 Micrograms, Lectithin (Inert Amt.) 10,000 Micrograms"; "Ribo Ton * * * A Tablet Contains: Carrot Powder, Parsley Powder, Spinach Powder, 500

Gammas Natural Riboflavin, Dextrose"; and "Java Ton Contains Soluble Coffee Lactose."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use for the following diseases, symptoms, and conditions for which the articles were prescribed, recommended, and suggested in advertising, sponsored by and on behalf of the manufacturer, packer, and distributor of the articles: *Fruitonya*—Insomnia due to nervousness, colds, too long menstrual flow, bad liver, and catarrh; *Neutraton*—poison glands, a condition of pus in the eyes, vomiting of babies, and liver conditions; *Hematon No. 1*—Anemia in thin people; *Hematon No. 2*—anemia in stout people and for blood building; *Phospho B Complex*—bad heart condition, poor memory, and low blood pressure; *Ribo Ton*—inflamed or tired eyes; and *Java Ton*—goiter.

Further misbranding, *Hematon No. 1*, Section 502 (a), the designation "Hematon No. 1" and the label statement "5 Vitamin Malt Tonic With Iron" were false and misleading since the article was not a blood tonic and did not possess tonic properties; and, *Hematon No. 2*, Section 502 (a), the designation "Hematon No. 2" was misleading since it created the impression that the article was a blood tonic, whereas it was not.

The *Fruitonya* was alleged also to be further misbranded under the provisions of the law applicable to foods as reported in notices of judgment on foods.

DISPOSITION: On February 24, 1949, the Miracle Food Co., claimant, filed a request for answers to certain interrogatories. The interrogatories were answered, and on November 17, 1949, the claimant having consented to the entry of a decree (and the court having found that the products were misbranded as alleged in the libel, except that no finding was made with respect to the allegation that the name "Fruitonya" was misleading within the meaning of Section 403 (a)), judgment of condemnation was entered and the court ordered that the products be destroyed.

2914. Misbranding of Catalyn, Cataplex A, Cataplex C, Cataplex A and C, Cataplex E, Cataplex F, Cataplex G, and Minaplex. U. S. v. 24 Packages, etc. (F. D. C. No. 27266. Sample Nos. 9548-K, 9549-K, 9551-K to 9556-K, incl.)

LIBEL FILED: June 22, 1949, Southern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of October 31, 1947, and March 23, 1949, from Milwaukee, Wis.

PRODUCT: 24 packages, consisting of 6 bottles, of *Catalyn*; 3 packages of *Cataplex A*; 1 bottle of *Cataplex C*; 3 bottles of *Cataplex A and C*; 2 packages of *Cataplex E*; 3 packages of *Cataplex F*; 4 bottles of *Cataplex G*; and 2 packages of *Minaplex*, at New York, N. Y., stored to the account of D. H. Urbanik, together with 25 printed forms reading, in part, "Deficiency Examination Questionnaire" and a mimeographed booklet entitled "Youth and Vitality Diet Class Notes," which accompanied the articles.

LABEL IN PART: (Bottle) "Catalyn V-P 710 * * * Concentrates From Alfalfa, Carrot, Beef and Fish Liver Lipoids, Yeast, Wheat Germ, Rice Bran, Liver, Mushroom, Green Peas (Whole Plant), Biologically Processed Corn * * * 120 Tablets"; (package) "Cataplex A Vitamin A Complex * * * Concentrates of Vitamin Factors from Alfalfa, Carrot, Beef Kidney, and Fish Liver Lipoids * * * 120 Tablets"; (bottle) "Cataplex C Vitamin C * * * Contains 100 U. S. P. Units of Vitamin C per Tablet with Naturally

Associated Factors from Alfalfa, Mushroom, and Bone Marrow * * * 120 Tablets"; (bottle) "Cataplex A and C Vitamin A & C * * * Each Tablet Contains 750 U. S. P. Units of Vitamin A and 100 U. S. P. Units of Vitamin C with naturally associated vitamin and enzyme factors from alfalfa, carrot, mushroom, bone marrow, beef kidney, and fresh liver lipoids * * * 120 Tablets"; (package) "Cataplex E Vitamin E * * * Concentrate of vitamin factors from the juice of green peas (whole plant) and natural mixed tocopherols (vitamin E) obtained from vegetable oils * * * 120 Tablets"; (package) "Cataplex F Vitamin F * * * Derived from essential unsaturated fatty acids, arachidonic, linolenic, linoleic from flax and beef lipoids. Each tablet contains 5 milligrams of organically combined iodine * * * 120 Tablets"; (bottle) "Cataplex G Vitamin G * * * Content of vitamin factors legally considered as necessary to human nutrition: Riboflavin 1 Mg. niacin 5 Mg. one-third daily requirement per tablet, for adults. With synergists, and extracts from yeast, sprouted grain, and calf brain * * * 120 Tablets"; and (package) "Minaplex * * * Organic Mineral Tablets Contains Colloidal Minerals of sea lettuce (Dulse) and alfalfa * * * 120 Tablets."

NATURE OF CHARGE: Misbranding (the articles were misbranded while held for sale after shipment in interstate commerce), Section 502 (a), certain statements in the questionnaire were false and misleading since they represented and suggested that the articles were effective in the treatment of the following diseases and conditions, whereas the articles were not so effective:

Catalyn.—Tiredness, insomnia, digestive distress after meals, intestinal gas, tendency to develop gastric ulcers, constipation, underweight, swollen ankles, dislocated joints, arch trouble, restless sleep, weakness in hot weather, eczema, allergies, gall bladder trouble, susceptibility to colds, cold sores, canker sores, cystitis, irritation in urinary tract, sensitivity to bright light, irritated eyes, nervousness, brittle nails, sexual impotence, falling hair, tendency to prostate trouble, menstrual dysfunction, menopausal disorders, albuminuria, glycosuria, fast pulse, slow pulse, high blood pressure, low blood pressure, chronic subnormal temperature, arrhythmia, fibrillation, anemia, pain in heart region, and heart beating with disturbing force after retiring.

Cataplex A.—Intestinal gas, swollen ankles, allergic susceptibilities, gall bladder trouble, susceptibility to colds, cold sores, canker sores, cystitis, irritation in urinary tract, sensitivity to bright light, irritated eyes, nervousness, sexual impotence, albuminuria, glycosuria, and high blood pressure.

Cataplex C.—Easy tiring, insomnia, intestinal gas, underweight, swollen ankles, dislocated joints, arch trouble, weakness in hot weather, susceptibility to eczema, allergic susceptibility, susceptibility to colds, cold sores, canker sores, cystitis, irritation in urinary tract, sensitivity to bright light, irritated eyes, nervousness, tendency to prostate trouble, menstrual dysfunction, menopausal disorders, albuminuria, fast pulse, slow pulse, high blood pressure, low blood pressure, chronic subnormal temperature, arrhythmia, fibrillation, tendency to anemia, tendency to pain in the heart region on exercise, and heart beating with disturbing force after retiring.

Cataplex E.—Easy tiring, digestive distress after meals, tendency to develop gastric ulcers, dislocated joints, arch trouble, susceptibility to eczema, sexual impotence, and menstrual dysfunction.

Cataplex F.—Easy tiring, digestive distress after meals, tendency to develop gastric ulcers, weakness in hot weather, susceptibility to eczema, allergic susceptibilities, gall bladder trouble, cold sores, canker sores, cystitis, infections of urinary tract, sensitivity to bright light, irritated eyes, easily broken nails

falling hair, sexual impotence, tendency to prostate trouble, menopausal disorders, albuminuria, glycosuria, high pulse rate, low pulse rate, high blood pressure, and chronic subnormal temperature.

Cataplex G.—Tendency to insomnia, gastric distress after meals, intestinal gas, tendency to develop gastric ulcers, swollen ankles, allergic susceptibilities, nervousness, easily broken nails, glycosuria, high pulse rate, high blood pressure, arrhythmia, fibrillation, tendency to pain in heart region on exercising, and heart beating with disturbing force after retiring.

Minaplex.—Constipation, dislocated joints, arch trouble, allergic susceptibilities, cold sores, canker sores, high pulse rate, high blood pressure, and heart beating with disturbing force after retiring.

Further misbranding, Section 502 (a), certain statements in the booklet were false and misleading since they suggested that the articles would be effective in the prevention and treatment of the following conditions, whereas the article would not be effective for such purposes:

All articles.—Congestion of nose, throat, chest, catarrhal conditions anywhere in the body, sinus trouble, bronchitis, asthma, colitis, arthritis, acne, eczema, hives, pimples, skin eruptions, misplaced organs, loss of muscular tone, general debility, premature aging, and declined vigor and function.

Cataplex A.—Kidney stones, bladder stones, and gall stones.

Cataplex C.—Aging and brittle arteries, aging tissues, degeneration, poor development of bones and teeth, pyorrhea, unhealthy gum tissues, unhealed wounds, susceptibility to infections, and weakened capillaries.

Cataplex A and C.—Stomach ulcers, infections of intestinal tract, colitis, and ulcerations in any part of the intestinal tract.

Cataplex E.—Cancer and unhealthy sex organs.

Cataplex F.—Dry skin and anemia.

Cataplex G.—Aging tissues and cells.

Further misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use for the conditions for which they were recommended by Helen Houston and D. H. Urbanik, their distributors, at New York, N. Y., between April 8 and 12, 1949.

DISPOSITION: July 22, 1949. Default decree of condemnation and destruction.

2915. Misbranding of Super Potency Ferro-Plus Liver, Iron, and Vitamin B Complex Capsules, Lackzoom's Garlic & Parsley Capsules in Cold Pressed Wheat Germ Oil, Lackzoom Pure Soybean Lecithin Capsules, Wheat Germ Oil Capsules, Amo-Tabs Amino Acid Tablets (Special Tablets), Lackzoom's "Supreme-A" Food Supplement Capsules, Lackzoom's Super C Tablets, Lackzoom's New Blue Label Hi-B Complex Tablets and Special Capsules. U. S. v. 142 Bottles, etc. (F. D. C. No. 27004. Sample Nos. 46655-K to 46662-K, Incl.)

LIBEL FILED: April 19, 1949, Western District of Pennsylvania.

ALLEGED SHIPMENT: The Savoy Drug & Chemical Co. shipped on or about August 24, 1948, from Chicago, Ill., a number of tablets in bulk which were labeled "Special Tablets * * * Yeast Amino Acids," a portion of which were repacked after receipt in Pittsburgh, Pa., into bottles labeled "Amo-Tabs Amino Acid Tablets."

The Strong, Cobb & Co., Inc., shipped on or about September 3, 1948, from Cleveland, Ohio, a number of tablets in bulk which were labeled "Special Capsules," a portion of which were repacked into bottles labeled "Tablets Lackzoom's New Blue Label Hi-B Complex."

The other above-named products were shipped by various firms between the approximate dates of November 10, 1948, and March 7, 1949, from New York, N. Y., Detroit, Mich., Cleveland, Ohio, and St. Louis, Mo.

PRODUCT: 171 bottles of *Super Potency Ferro-Plus Liver, Iron, and Vitamin B Complex Capsules*; 164 bottles of *Lackzoom's Garlic and Parsley Capsules in Cold Pressed Wheat Germ Oil*; 37 packages of *Lackzoom Pure Soybean Lecithin Capsules*; 300 bottles of *Wheat Germ Oil Capsules*; 40,800 tablets, from which 15,800 tablets had been repackaged into 265 bottles labeled "Amo-Tabs Amino Acid Tablets," and from which 25,000 tablets were remaining in a drum labeled "Special Tablets * * * Yeast Amino Acids"; 295 bottles of *Lackzoom's "Supreme-A" Food Supplement Capsules*; 260 bottles of *Lackzoom's Super C Tablets*; and 18,100 tablets, from which 4,100 tablets had been repackaged into 41 bottles labeled "Tablets Lackzoom's New Blue Label Hi-B Complex," and from which 14,000 tablets were remaining in a drum labeled "Special Capsules."

The products were in the possession of the Lackzoom Health Stores, also known as Lackzoom Stores, at Pittsburgh, Pa. The bottles and packages were in various sizes ranging from 35 to 400 capsules or tablets. There were a number of copies of a folder entitled "Keep Healthy" and a booklet entitled "Lackzoom Hi-Lites" on display at a number of the Lackzoom Health Stores.

LABEL, IN PART: "Super Potency Ferro-Plus Liver, Iron and Vitamin B Complex Capsules Each Capsule contains the equivalent of Liver Substance 1:7 7 Grains, Iron (Ferrous) Sulfate 5.2 Grains, Vitamin B₁ 1665 U. S. P. Units (Thiamin Chloride—5 Mg.), Vitamin B₂ (Riboflavin) 4000 Mcg. (1.0 Mg.), Vitamin B₆ (Pyridoxine Hydrochloride) 50 Mcg. (0.05 Mg.), Calcium Pantothenate 2000 Mcg. (2.0 Mg.), Niacinamide 30 Mg."; "Capsules Lackzoom's Garlic & Parsley in Cold Pressed Wheat Germ Oil Each capsule contains approx. 2500 Mg. of clean fresh parsley and peeled garlic (moisture removed) suspended in approx. 155 Mg. of cold pressed wheat germ oil"; "Lackzoom Pure Soybean Lecithin * * * Each Capsule Contains 4 Grains Lecithin"; "Wheat Germ Oil Capsules"; "Amo-Tabs Amino Acid Tablets Three Tablets Contain: Arginine (1-hydrochloride) 1.0 Mg., Cystine (1-hydrochloride) 0.1 Mg., Histidine (1-hydrochloride) 0.1 Mg., Leucine (L—) 1.0 Mg., Isoleucine (dl) 1.0 Mg., Lysine (1-hydrochloride) 0.5 Mg., Methionine (dl) 1.0 Mg., Phenylalanine (dl) 0.1 Mg., Threonine (dl) 0.1 Mg., Tryptophane (dl) 0.1 Mg., Valine (dl) 0.1 Mg. in a base of high-protein brewer's yeast and excipients necessary to prepare"; "Special Tablets * * * Yeast Amino Acids"; "Capsules Lackzoom's 'Supreme-A' Food Supplement Each Capsule Contains not less than 25,000 USP Units Vitamin A"; "Tablets Lackzoom's Super C Each tablet contains not less than 2000 U. S. P. Units Vitamin C (100 Mg. Ascorbic Acid)"; "Tablets Lackzoom's New Blue Label Hi-B Complex Each tablet contains: Vitamin B₁ 500 USP Units, Vitamin B₂ (G) 1000 Micrograms, Vitamin B₆ 125 Micrograms, Calcium Pantothenate 250 Micrograms, Niacin 10000 Micrograms and such other factors of the Vitamin B Complex as are found in the concentrates of liver and yeast contained in these tablets"; and "Special Capsules Vitamin B₁ (thiamin chloride) 1.5 Mg., Vitamin B₆ (pyridoxine hydrochloride) .125 Mg., Niacin 10.00 Mg., Calcium Pantothenate .25 Mg., Liver & Yeast Base."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the folder and booklet with respect to the articles, other than the 25,000- and the 14,000-tablet lots remaining in the drums, were false and misleading since the articles were not effective for the purposes stated and implied:

Super Potency Ferro-Plus Liver, Iron, and Vitamin B Complex Capsules.—“Can’t Sleep Nights? Lackzoom Ferro-Plus. Many people can’t sleep nights, are always tired, weak or pale because they are not getting enough iron to build rich red blood. They may be suffering victims of nerves because they are deficient in Thiamin * * * Nervousness, Sleeplessness, Anemia and Indigestion, authorities say, often spring from a deficiency of either iron, Thiamin or other B-Complex Vitamins. Here is an easy way to insure a sufficient supply of these factors.”

Lackzoom’s Garlic & Parsley Capsules in Cold Pressed Wheat Germ Oil.—“High Blood Pressure Ills Lackzoom Garlic and Parsley Proves Great Benefit. For centuries the vital role of garlic in the treatment of High Blood Pressure has been recognized by many people. Garlic is also recommended as affording marked relief in many cases of varicose veins, infections and intestinal poisoning. Parsley is especially rich in the organic iron which is necessary for making red blood, and also as a source of Vitamin A.”

Lackzoom Pure Soybean Lecithin Capsules.—“Drowsiness Nervousness Lack of Pep May Be Due to Lack of Lecithin! Lackzoom Lecithin. Lecithin is * * * important to the health of the brain and nerves. It is also believed to increase the production of red corpuscles and is therefore largely used in the treatment of anemia.”

Wheat Germ Oil Capsules.—“More Pep and Energy Lackzoom Wheat Germ Oil Elixir of Life * * * the ‘anti-sterility’ vitamin * * * has an effect on the assimilation of lime and magnesium for bones and teeth and also apparently on the reproductive functions of both male and female. Helps to promote vigor and growth, stimulates various glandular functions, sharpens intelligence and promotes mental alertness. A recent national magazine article reports relief in test cases of heart ailment sufferers.”

Amo-Tabs Amino Acid Tablets.—“When one or more of these 10 ‘essential’ Amino Acids are left out of our diet we suffer certain ‘deficiency’ symptoms; lowered vitality, poor blood circulation, lack of pep and energy and poor resistance against infection, colds and other respiratory diseases. If the diet is permitted to be lacking in Amino Acids for a prolonged time, serious mental and nervous disorders can result. Certain amino acids are known to have an effect on the function of both male and female sex organs in the body. Serious lack is believed in some cases to be responsible for cataract, failure of hair growth and premature old age. Deficiency in children can interfere with proper growth and bone formation, teeth development or to be the cause of rickets. The only way to be absolutely sure the body is not being deprived of any of these ten essential amino acids is to take them daily in concentrated tablet form.”

Lackzoom’s “Supreme-A” Food Supplement Capsules.—“Colds, Sinus Troubles, Poor Eyesight, Bad Complexion If You Have These Symptoms You Need More Vitamin A—says Walter Eddy, famous vitamin authority * * * A is the vitamin most directly important to good eyesight * * * Also it heightens resistance to colds and sinus infections and favors growth in young children * * * Lackzoom Supreme-A Concentrate Vitamin A is described above. When a marked deficiency is known to exist and quick improvement is hoped for, much more than the normal intake of Vitamin A can be used with good results. Lackzoom Supreme-A Concentrate is valuable in such cases.”

Lackzoom’s Super C Tablets.—“Infections Slow Healing Varicose Veins Arthritis May Be Caused by Vitamin C Deficiency Lackzoom Vitamin C * * * slow healing of minor wounds, and too easy infection may be symptoms of deficiency.”

Lackzoom's New Blue Label Hi-B Complex Tablets.—"Nervousness Irritability. Loss of Pep Run Down Lackzoom Hi-B Complex Formerly * * * distinguished as the nerve and brain-food vitamin * * * Nervousness, loss of energy, constipation, indigestion, and neuritis are among the symptoms that may indicate Vitamin-B deficiency."

The above articles were misbranded while held for sale after shipment in interstate commerce.

Further misbranding, Section 502 (f) (1), the labeling of the 14,000-tablet lot of the *Special Capsules* failed to bear adequate directions for use for the purposes for which the tablets were intended since the labeling failed to bear adequate directions for use for the conditions and diseases for which the tablets were offered in the booklet entitled "Lackzoom Hi-Lites," namely, nervousness, irritability, loss of pep, run-down condition, loss of energy, constipation, indigestion, and neuritis. The 14,000-tablet lot of the *Special Capsules* was misbranded when introduced into and while in interstate commerce.

The 25,000-tablet lot in the drum labeled "Special Tablets * * * Yeast Amino Acids" was alleged to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: April 26, 1949. David B. Shakarian, claimant, having admitted that the allegations of the libel were true, judgment was entered ordering that the products be released under bond for relabeling under the supervision of the Federal Security Agency.

DRUGS ACTIONABLE BECAUSE OF THE PRESENCE OF A HABIT-FORMING NARCOTIC WITHOUT WARNING STATEMENT*

2916. Misbranding of Mothersill's Airsick Remedy and Mothersill's Seasick Remedy. U. S. v. 45 dozen Packages, etc. (F. D. C. No. 21680. Sample Nos. 43647-H, 43648-H, 71033-H.)

LIBEL FILED: November 26, 1946, Southern District of California; amended libel filed May 10, 1949.

ALLEGED SHIPMENT: On or about September 3 and 23 and October 11 and 14, 1946, by F. T. Hopkins & Son, from New York, N. Y.

PRODUCT: 45 dozen packages of *Mothersill's Airsick Remedy* and 272 dozen packages of *Mothersill's Seasick Remedy* at Los Angeles, Calif.

LABEL, IN PART: "Mothersill's Airsick Remedy * * * Each capsule contains 1½ grains of trichlor-tertiary-butyl-alcohol, a chloroform derivative, ¼₄₀₀ grain hyoscine hydrobromide, caffeine and suitable flavorings" and "Mothersill's Seasick Remedy * * * Each Capsule contains 2 grains of trichlor-tertiary-butyl-alcohol, a chloroform derivative, ¼₄₀₀ grain hyoscine hydrobromide, caffeine and suitable flavorings."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Guaranteed not to contain morphine, chloral, cocaine, opium, coal tar products or their derivatives," which appeared on the label of both articles, was misleading since it suggested and created the impression that the articles contained no injurious drugs, whereas the articles contained hyoscine hydrobromide and chlorobutanol, which are capable of producing injurious effects.

*See also No. 2912.

Further misbranding, Section 502 (c), the information required by law to appear on the label was not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render such information likely to be read and understood by the ordinary individual under customary conditions of purchase and use since the statement of the quantity of the contents of the package appeared inconspicuously placed and in small type; since the name of the habit-forming ingredient, chlorobutanol, was declared by the name "trichlor-tertiary-butyl-alcohol," a designation which is not likely to be understood by the ordinary individual under customary conditions of purchase and use, and the quantity or proportion thereof, namely, $1\frac{1}{2}$ grains and 2 grains, respectively, appeared inconspicuously in small type; and since the name and quantity or proportion of the ingredient, hyoscine hydrobromide, a derivative of hyoscine, and the name of the active ingredient, caffeine, appeared inconspicuously in small type on the label.

Further misbranding, Section 502 (d), the articles were drugs for use by man and contained chlorobutanol, a chemical derivative of chloral, which derivative has been found by the Administrator of the Federal Security Agency, after investigation, to be and by regulations designated as habit forming; and the labels of the articles failed to bear immediately following the name of the article, the common or usual name of the article and in juxtaposition therewith, the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the labeling of the articles failed to bear such adequate warnings against unsafe dosage and duration of administration in such manner and form as are necessary for the protection of users since the articles contained hyoscine hydrobromide; and the labeling of the articles failed to warn that use of the articles should be discontinued if dizziness or blurring of vision occurred, and that use in excess of the recommended dosage may cause serious nervous disturbance.

DISPOSITION: F. T. Hopkins & Son appeared as claimant and, in accordance with the agreement of the parties, the libel proceedings were ordered removed to the District of New Jersey for trial. On November 29, 1949, the claimant having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be destroyed.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2917. Adulteration of P & V Low Mallow (crude drug). U. S. v. 2 Drums
* * * (F. D. C. No. 27669. Sample No. 14195-K.)

LIBEL FILED: August 12, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about August 4, 1948, from Jersey City, N. J.

PRODUCT: 2 50-pound drums of *P & V Low Mallow* at Chicago, Ill.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: November 2, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2918. Adulteration and misbranding of chorionic gonadotropic hormone. U. S. v. 54 Cartons, etc. (F. D. C. No. 27279. Sample Nos. 11292-K, 11293-K.)

LIBEL FILED: June 6, 1949, Eastern District of New York.

ALLEGED SHIPMENT: On or about January 14 and February 20, 1948, from Philadelphia, Pa.

PRODUCT: 54 cartons and 75 cartons, each carton containing 1 unlabeled vial, of *chorionic gonadotropic hormone* at Richmond Hill, N. Y. Each lot was accompanied by sticker labels on the shipping cartons which represented that the 54-carton lot contained 500 International Units of *chorionic gonadotropic hormone* per vial and that the 75-carton lot contained 1,000 International Units of *chorionic gonadotropic hormone* per vial. The vials and the 1-vial cartons were labeled after shipment in interstate commerce.

Analyses showed that the product (both lots) contained less than half of the declared amounts of *chorionic gonadotropic hormone*.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported to possess.

Misbranding, Section 502 (a), the following label statements were false and misleading as applied to the article, which contained less than half of the declared amounts of *chorionic gonadotropic hormone*: (54-carton lot) "Each 1 cc will contain 500 international units of chorionic gonadotropic hormone when 10 cc of triple distilled water is added to this vial" and (75-carton lot) "Each 1 cc will contain 100 international units of chorionic gonadotropic hormone when 10 cc of triple distilled water is added to this vial."

The article was adulterated and misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: August 9, 1949. Default decree of condemnation and destruction.

2919. Adulteration and misbranding of surgical dressings. U. S. v. 126 Packages, etc. (F. D. C. No. 28341. Sample Nos. 33682-K, 33683-K.)

LIBEL FILED: November 22, 1949, Northern District of California.

ALLEGED SHIPMENT: On or about October 4, 1949, by Surgical Dressings, Inc., from Boston, Mass.

PRODUCT: 126 packages, each containing 1 roll, of bandage 1½" x 12" and 114 packages, each containing 1 roll, of bandage 2" x 24" at Sacramento, Calif. Examination showed that the product was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: "Sterilastic Dressing Bandage."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements appearing on the package labels of the article were false and misleading as applied to an article which was not sterile: (1½" x 12" size) "Sterilastic * * * First Aid Wound Protection * * * Both the Sterilastic and the Gauze in this Package have been sterilized * * * Surgical Dressing" and (2" x 24" size) "Sterilastic First Aid Bandage * * * Surgical Dressing * * * The gauze supplied with Sterilastic may be used in an emergency."

DISPOSITION: December 8, 1949. Default decree of condemnation and destruction.

2920. Adulteration and misbranding of prophylactics. U. S. v. 78 Gross * * *
(F. D. C. No. 27429. Sample No. 44931-K.)

LIBEL FILED: June 21, 1949, District of Minnesota.

ALLEGED SHIPMENT: On or about May 25, 1949, by Hughes Products, Inc., from Memphis, Tenn.

PRODUCT: 78 gross of *prophylactics* at Minneapolis, Minn. Examination of samples showed that 10.38 percent were defective in that they contained holes.

LABEL, IN PART: "Texide Prophylactic Manufactured by L. E. Shunk Latex Prod., Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "For Your Protection" were false and misleading as applied to an article containing holes.

DISPOSITION: October 21, 1949. Default decree of destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2921. Misbranding of Nue-Ovo. U. S. v. 600 Units, etc. (and 3 other seizure actions). Trial by jury. Verdict for Government. Decree of condemnation and destruction. Judgment affirmed on appeal to court of appeals. Certiorari denied by United States Supreme Court. (F. D. C. Nos. 14342, 16711, 20239, 20768. Sample Nos. 3830-F, 80924-F, 27846-H, 45063-H, 45068-H, 58379-H.)

LIBELS FILED: On or about November 8, 1944, August 6, 1945, and June 18 and August 29, 1946, Western District of Missouri, Western District of Washington, and Southern District of California.

ALLEGED SHIPMENT: The product was shipped by Research Laboratories, Inc., from Portland, Oreg., between the approximate dates of June 27, 1944, and August 24, 1946, and quantities of printed matter were shipped by the above firm, from Portland, Oreg., on or about April 16, 1945, and February 1 and June 1946. Quantities of printed matter also were shipped by Nue-Ovo, Inc., from Chicago, Ill., on or about July 19, 1943, and April 7 and August 8, 1944.

PRODUCT: 600 units, each containing 3 bottles; 71 packages, each containing 3 bottles; and 160 cases, each containing 18 bottles, of *Nue-Ovo* at Kansas City, Mo., Seattle, Wash., and Los Angeles, Calif., together with copies of circulars entitled "Information on Nue-Ovo and its Value in Arthritic and other Rheumatoid Symptoms" and "Read and see what Nue-Ovo has done for this man," copies of a circular letter headed "California Division Research Laboratories, Inc." and beginning "We thank you for your inquiry regarding Nue-Ovo in the treatment of Arthritic and Rheumatic symptoms, which was used successfully by Mrs. Emma Ives," and a number of placards reading, in part, "Are you suffering from arthritis or rheumatism?" Analysis disclosed that the product contained water, sugars, sodium benzoate, and extracts of plant materials, including a caffeine-bearing drug, such as kola nut, and licorice and cinnamon, and a laxative drug, such as cascara sagrada, and that certain portions of the product also contained sodium salicylate and a minute amount of vitamin B₁.

*See also Nos. 2913-2916, 2918-2920.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars, circular letter, and placards were false and misleading. The nature of the false and misleading statements is set forth in the opinion of the circuit court of appeals, *supra*.

DISPOSITION: Research Laboratories, Inc., having appeared as claimant and filed a motion for the removal of the libel proceedings in the Western District of Missouri, an order was entered on March 1, 1945, by the court for that district, directing that the proceedings be removed for trial to the District of Oregon. Thereafter, a motion to vacate such order was filed on behalf of the Government, on the grounds that the court was without authority to transfer the case to the district in which the claimant had its home office.

On March 23, 1945, after consideration of the briefs of the parties, the following opinion was handed down:

REEVES, *District Judge*: "On the first day of March 1945 this court entered an order removing and transferring the above entitled cause to the district court of the United States sitting at Portland, Oregon, for trial. This is the place intervenor's business is located. The order was made pursuant to motion filed by the intervenor for removal and transfer of the libel proceeding pursuant to provisions of Section 334 (a), Title 21 U. S. C. A. The language of the motion conforms to the statutory requirements, as follows:

In any case where the number of libel for condemnation proceedings is limited * * * the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

"At the time the order was made the United States Attorney appeared with counsel for the intervenor or claimant and then insisted that the only order that could be properly made was one transferring and removing the case to the Western District of Washington, being a district of reasonable proximity to the claimant's principal place of business. The court was then of the opinion that the statute contemplated a place for holding court as near to the principal place of business of the claimant as practicable. Such a place of holding court was at Portland, Oregon. A hurried interpretation of the statute seemed to warrant the court in removing the case for trial to that point. The District Attorney did not agree to the order and, as indicated, has subsequently filed a motion to vacate the order of removal. The parties have favored the court with briefs and suggestions in support of their respective contentions. Congressional records showing the history of the legislation indicate that the Senate attempted to provide that a case of this kind might be removed and transferred to the district court in which claimant's principal place of business was located, while, on the other hand, the House of Representatives attempted to provide that the removal could be made only to a district court of a state contiguous to the state of claimant's principal place of business. Both the Senate and House receded from their several extreme positions. The Senate no longer contended that the transfer should be made to a state contiguous to that of the claimant's domicile. The compromise involved the use of the words 'a district of reasonable proximity to the claimant's principal place of business.' In order to give a proper meaning to the statute, in view of the concessions made by the two legislative bodies, a district of reasonable proximity would mean a district other than that of the domicile of the claimant, whether in the same state or a contiguous state. Oregon has but one district, whereas the State of Washington has two districts. The Western District of Washington, Southern Division, is a district of 'reasonable proximity to the claimant's principal place of business.'

"1. A statement of the facts and the law, as above, suggests a proper interpretation of the statute and what order should be made in the case. This is not a case of first impression.

"In the case of *United States v. 6 dozen bottles, etc.*, 55 Fed. Supp. 458, Judge Duffy of the District Court of the Eastern District of Wisconsin, was presiding in a similar case. That case, however, had been transferred to his district from one of the district courts in the State of Washington. The claimant in that case had originally applied to one of the district judges in one of the districts of Washington to transfer the case to the Northern District of Illinois for the reason that the claimant's principal place of business was in Chicago. The District Judge declined to transfer the case to the Northern District of Illinois but did order its removal or transfer to the Eastern District of Wisconsin, being a district of reasonable proximity to the claimant's place of business. After the transfer to that district of reasonable proximity the claimant renewed its motion for a transfer to the Northern District of Illinois. While District Judge Duffy ruled that the claimant had exhausted his right of removal as having been accorded by statute but one removal, nevertheless he took occasion to say:

Manifestly, claimant's application for removal to the district court in Illinois was not granted by the district court in Washington, *because the same would not have been and is not authorized.* In the absence of stipulation between the parties, *the power of removal of the court of original jurisdiction is limited and restricted.* Such court is required to order removal to "a district of reasonable proximity to the claimant's principal place of business." Accordingly, it would have been beyond the power of the district court in Washington to have removed this proceeding to the designated district court in Illinois.

"2. Moreover, in this case, the claimant apparently so interpreted the statute for the reason that, in its motion to transfer it said:

Intervenor further states that the United States District Court next closest to Intervenor's place of business is the District Court of the United States for the District of Washington, Western District, Southern Division, sitting at Tacoma, Washington, which said district court is approximately 150 miles from Portland, Oregon.

Wherefore, Intervenor prays that said cause be transferred and removed from this Court to a district of reasonable proximity to Intervenor's principal place of business.

It will be observed that the intervenor does not ask that the case be transferred to the district in which the claimant's principal place of business is located.

"In view of the above, the order of removal transferring the case for trial to the District Court of Oregon, sitting at Portland should be amended so that the order of removal will be to the Western District of Washington, Southern Division, at Tacoma, Washington, and it will be so ordered."

In accordance with the above opinion, an order was entered on March 23, 1945, providing that the order of March 1, 1945, be vacated and that the libel proceedings in the Western District of Missouri be removed to the Southern Division of the Western District of Washington.

On April 23, 1945, the claimant filed in the United States District Court for the Western District of Washington, Southern Division, exceptions to the libel proceedings so removed, based on the grounds (1) that the libel failed to state facts sufficient to constitute a cause of action and (2) that the printed matter did not accompany the product or constitute labeling of the product.

On March 25, 1946, after consideration of the arguments of counsel, an order was entered overruling and denying the exceptions to the libel. Thereafter, on stipulations of the parties, an order was entered directing the consolidation for trial, in the Western District of Washington, of the case removed from the Western District of Missouri, with the two libel proceedings originally instituted in the Western District of Washington and the libel proceeding originally instituted in the Southern District of California.

An answer was filed by the claimant, denying the pertinent allegations of the libel; and on October 22, 1946, the case came on for trial before the court and jury. On November 1, 1946, the trial was concluded with the return of a verdict in favor of the Government. On November 22, 1946, judgments of condemnation were entered and it was ordered that the circulars be destroyed and that the product be subsequently disposed of as ordered by the court.

The case was appealed to the Court of Appeals for the Ninth Circuit; and

on April 2, 1948, the following opinion was handed down by that court, affirming the judgment of the district court:

GARRECHT, *Circuit Judge*: "In four cases consolidated for trial, judgments and decrees were entered condemning and ordering destroyed quantities of a proprietary drug known as 'Nue-Ovo' and certain written material alleged to constitute the labeling thereof. The action of the court below was taken pursuant to libels alleging misbranding, under 21 USCA § 352 (a). From the judgments and orders referred to, the present appeals have been taken by the intervenor below, as claimant of the property seized.

"The appellant, an Oregon corporation, has engaged in the manufacture, sale, and distribution of proprietary drug products known as 'Nue-Ovo,' 'Sal Trag,' and 'Burvidin' continuously since 1925. The formulas of the products have been changed from time to time, and the merchandise now under seizure differs from products of the same name involved in previous litigation.

"Nue-Ovo is sold direct to consumers. In concentrated form, called 'Sal-Trag,' it is sold to licensed physicians. The products are manufactured at Portland, Oregon, and shipped to purchasers and distributors in most of the states west of the Mississippi River. The appellant's direct sales program involves extensive use of advertisements in daily and weekly newspapers and similar publications. In general, these advertisements solicit mail inquiries regarding the effectiveness of Nue-Ovo in the treatment of arthritis, neuritis, rheumatism, sciatica, and lumbago, to which inquiries the appellant replies by mail. The advertisements referred to are not, of course, part of the labeling.

"In November, 1944, a libel was filed in the United States District Court for the Western District of Missouri, Western Division, pursuant to which there were seized by the United States Marshal about 600 units of Nue-Ovo, each unit containing three bottles. Some of the unit cartons are labeled in part:

Active Ingredients: An aqueous extraction of Plume Thistle, Burdock, Quassia, Sage, Cinnamon, Horehound, Dandelion, Kola Nut, Ginseng, Althea, Cascara and Licorice.

This is the regular Nue-Ovo Formula to which have been added laxatives. Less than one-half of one per cent Sodium Benzoate added as a preservative.

Other unit cartons are labeled in part:

This is the regular Nue-Ovo formula to which have been added Cascara, Licorice and Sodium Salicylate. Less than one half of one per cent Sodium Benzoate added as a preservative. Vitamin B1 added.

"The libel alleges that 600 units were shipped by the Appellant on or about June 27, 1944, and August 2, 1944, from Portland to Crown Drug Company, Kansas City, Missouri.

"Pursuant to the same libel there were also seized at the same time stocks of circulars entitled 'information on Nue-Ovo and its value in Arthritic and other Rheumatoid symptoms.' The circulars were alleged to have been shipped in interstate commerce on or about April 7 and August 8, 1944, from Chicago, Illinois, by Nue-Ovo, Inc.—not the appellant herein—to the Crown Drug Company at Kansas City.

"The libel alleges that:

The article is misbranded within the meaning of 21 U. S. C., 352 (a) in that the statements in the attached Exhibits "A" and "B" which appear in the labeling of the article . . . are false and misleading in this, that such statements represent and suggest and create in the mind of the reader thereof, the impression that the article of drug, Nue-Ovo, is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago, whereas, the article is not effective in the treatment of such conditions.

"Other seizures were made later pursuant to libels following the same general pattern as the foregoing.

"The proceedings were all removed to the court below, where they were consolidated for trial in accordance with the provisions of 21 USCA § 334 (b).

"The court below entered a pre-trial order which specified as an agreed fact that 'the labeling alleged in the several libels constituted the labeling of the product seized.'

"The agreed issues were stated in the pre-trial order as follows:

1. Whether or not the Nue-Ovo under seizure is ineffective in the treatment of arthritis, rheumatism, neuritis, sciatica, or lumbago.
2. Whether or not the labeling under seizure suggests to the user that the Nue-Ovo is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, or lumbago.

3. Whether or not the product is misbranded by reason of the labeling.

"The appellant admitted that the labeling represented the product to be effective. Thus the misbranding and the ineffectiveness of the product were the issues to be litigated.

"Summarized, the appellant's attacks upon the judgment below are as follows:

1. The court below erred in submitting issues to the jury, since every statement in the labeling as to the effectiveness of the product is a statement of opinion, and at the conclusion of the case the record showed nothing more than a difference of opinion among qualified medical experts as to the effectiveness of the product.
2. The court erred in receiving testimony intended to show a misleading of the witnesses by material that was not part of the labeling seized.
3. The court erred in instructing the jury as to the elements to be taken into account in determining whether the labeling is misleading, under 21 USCA 321 (n), *infra*.
4. If it should be held that the court did not err in giving an instruction based upon 21 USCA 321 (n), *infra*, the court's denial of the appellant's motion for the release of the product under bond was an abuse of discretion.
5. As applied by the court the statute is unconstitutional.

"If the first four objections urged by the appellant are found to be untenable, the fifth must fall of its own weight and need not be discussed.

1. *The Rule in the McAnnulty Case*

"The appellant bases its first contention upon a line of decisions commencing with *American School of Magnetic Healing v. McAnnulty*, 187 U. S. 94, 105-106. There the court said:

As the effectiveness of almost any particular method of treatment of disease is, to a more or less extent, a fruitful source of difference of opinion, even though the great majority may be of one way of thinking, the efficacy of any special method is certainly not a matter for the decision of the Postmaster General within these statutes relative to fraud. Unless the question may be reduced to one of fact as distinguished from mere opinion, we think these statutes cannot be invoked for the purpose of stopping the delivery of mail matter.

"Although the McAnnulty case was decided four years before the passage of the original Food and Drugs Act of June 30, 1906, c. 3915, 34 Stat. 768, the doctrine there announced was applied to the misbranding of drugs in *United States v. Johnson*, 221 U. S. 488, 498-499 (1911), and in *Seven Cases of Eckman's Alternative v. United States*, 239 U. S. 510, 517 (1916).

2. *Three Limitations to the McAnnulty Rule*

"It should be borne in mind, however, that the McAnnulty case, *supra*, was heard on a demurrer and involved the Postmaster General's power to decide what was in reality a medical question, as to which he would presumably have no professional training.

"It cannot be assumed that the Supreme Court intended to reach out a dead hand over the power of Congress to pass legislation in the future setting up a well-equipped Federal agency capable of arriving at a professional conclusion as to the adulteration or misbranding of drugs 'when introduced into or while in interstate commerce.' 21 USCA § 334 (a). In the McAnnulty case the court not only pointed out that 'as the case arises on demurrer, all material facts in the bill are of course admitted,' but throughout the opinion doubt was expressed as to the qualifications of a *postmaster general* to pass on medical questions.

"In the excerpt which we have already quoted, the Supreme Court expressed the view that 'the efficacy of any special method [of treatment of disease] is certainly not a matter for the decision of the Postmaster General within these statutes relative to fraud.' Again, on page 105 of the opinion, referring to the place of electricity in therapeutics, the court pointedly asks: 'Was this kind of question intended to be submitted for decision to a Postmaster General, . . . ?'

"On the following page, the court thus summarized its holding as to the Postmaster General's power under the mail fraud statutes:

Other instances might be adduced to illustrate the proposition that these statutes were not intended to cover any case of what the Postmaster General might think to be false opinions, but only cases of actual fraud in fact, in regard to which opinion formed no basis.

"Even in that case, however, the court conceded that the Postmaster General might make a showing that fraud was being committed:

In overruling the demurrer we do not mean to preclude the defendant from showing on the trial, if he can, that the business of complainants as in fact conducted amounts to a violation of the statutes as herein construed. [Cf. Leach 1. Carlile, 258 U. S. 139, 139, 140.]

"And in Seven Cases of Eckman's Alternative v. United States, supra, 239 U. S. at page 518, Mr. Justice Hughes said:

It cannot be said, for example, that one who should put inert matter or a worthless composition in the channels of trade, labeled or described in an accompanying circular as a cure for disease when he knows it is not, is beyond the reach of the law-making power. Congress recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion but constitute absolute falsehoods and in the nature of the case can be deemed to have been made only with fraudulent purpose.

"In contrast to the meager technical facilities for the determination of medical questions possessed by the Postmaster General—at least at the time that the McAnnulty case was decided—we find that the Federal Security Agency has at its disposal almost unlimited professional resources with which to carry out its investigations in the enforcement of the Federal Food, Drug, and Cosmetic Act of June 25, 1938, c. 675, 52 Stat. 1040, 21 USCA § 301 et seq. Typical of this elaborate set-up are the provisions of 21 USCA § 372 (a):

The Administrator is authorized to conduct examinations and investigations for the purposes of this chapter through officers and employees of the Agency or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Administrator as an officer of the Agency. [Emphasis supplied.]

"As we shall disclose in our discussion of the evidence hereinafter, this extensive professional implementation authorized by the statute under consideration was fully utilized in the case at bar.

"In view of the foregoing, it could well have been reasoned *a priori* that the impact of the McAnnulty case would be carefully limited in later decisions. And that is precisely what has occurred.

"As was said in United States v. 7 Jugs, etc., of Dr. Salsbury's Rakos (DC Minn.), 53 F. Supp. 746, 759, heavily relied upon by the appellant itself:

Moreover, it must be obvious that tremendous advancements in scientific knowledge and certainty have been made since the rule in the McAnnulty case was first announced. Questions which previously were subjects only of opinion have now been answered with certainty by the application of scientifically known facts. In the consideration of the McAnnulty rule, courts should give recognition to this advancement.

(a) Jury May Consider Testimony as to Actual Experiments

"Much of the appellee's evidence in the instant case consisted of 'controlled clinical studies' conducted by eminently qualified physicians and surgeons.

"Dr. Frances Baker, Director of the Department of Physical Medicine at the University of California, whose professional qualifications appear to be highly impressive testified at great length regarding a clinical study that she made in 1944 with Nue-Ovo that contained cascara and licorice, but not B-1 and salicylate. The study was made on patients in the orthopedic clinic at the University of California Hospital. At the end of two months, five of the patients 'were no better at all' and 'one felt better.' As the result of her studies, Dr. Baker testified that she thought that Nue-Ovo 'offers us nothing that is of value in the treatment of arthritis.' She expressed similar opinions as to Nue-Ovo's effectiveness in cases of lumbago, sciatica, neuritis, and rheumatism, and stated that the addition of sodium salicylate and Vitamin B-1 in quantities found in one type of Nue-Ovo would not 'give us any value whatever.'

"Dr. John H. Wheeler is a practicing physician in Kansas City, Missouri, and is on the teaching staff of the University of Kansas, in Kansas City, Kansas. In 1944, at the request of the Food and Drug Administration in Kansas City,

he made a study of Nue-Ovo in the Out-Patient Department of the University of Kansas. The type of Nue-Ovo that he used was that containing cascara and licorice, without the B-1 and salicylates. Six patients were asked to continue the medicine for six weeks. Dr. Wheeler testified that the medicine had 'no effect whatsoever' on three patients, and two patients stated that they 'were of the opinion . . . that they were no worse.' On the day of his return, the sixth patient 'felt that he had definitely improved while taking his Nue-Ovo,' but 'was complaining of some new pains involving both knees.' This sixth patient, however, made that report ten months after starting the medication with Nue-Ovo, and still had some of the six weeks' supply of the medicine left.

"In 1940, Dr. Wheeler 'had experience' with Nue-Ovo with no added cascara or licorice with twenty-three patients, nine of whom took the preparation for as long as three months. Some took it for as short a period as two weeks, in one case because the discomfort was so great that the patient desired some other type of medication. Of the twenty-three cases, there were eighteen upon whom Nue-Ovo had no 'effect whatsoever,' three were 'questionable, in that perhaps their symptoms had improved slightly over the . . . previous period of nine months,' and 'two were definitely of the opinion that they felt better.' Based upon his total experience with the product in 1944 and the product in 1940, Dr. Wheeler's opinion was that, with or without cascara, licorice, or sodium salicylate or thiamine in the amount stipulated, Nue-Ovo's 'effectiveness is nil' in the treatment of arthritis, rheumatism, lumbago, neuritis, and sciatica.

"Testimony of experts that is based upon tests or experiments made by them does not come within the ambit of the McAnnulty rule. In *Elliott Works v. Frisk* (DC Iowa), 58 F. 2d 820, 825, the problem was fully and lucidly discussed:

Complainants are mistaken in their claim that the only evidence introduced as against them was mere opinions of witnesses and that the opinion of the expert for the government should not be considered as substantive evidence. In this contention complainants reply upon the case of *American School of Magnetic Healing v. McAnnulty*, 187 U. S. 94, 23 S. Ct. 33, 47 L. Ed. 90. The facts here are entirely different from what they are in that case, which arose on a demurrer wherein all the material facts averred in the bill were admitted for the purpose of the hearing. It may be conceded that the court there held that mere matters of opinion on which witnesses might vary in their conclusions would not substantiate a fraud order such as is here under consideration; but the finding of the solicitor in this case is not based on opinions, but upon a scientific investigation, findings, and tests made by the United States Bureau of Standards. Opinions of experts when founded upon known scientific facts are not to be considered the same as opinions of laymen, but are considered by the courts as substantive evidence. (Cases cited.) However, the evidence upon which the facts here were found was not alone based upon such scientific opinions, but upon tests made and facts actually disclosed by independent research of experts in an outstanding scientific bureau of the national government. [See also *Kar-Ru Chemical Co. v. United States* (CCA 9), 264 F. 921, 928; *United States v. Lesser* (CCA 2), 66 F. 2d 612, 616; *United States v. 7 Jugs, etc., of Dr. Salsbury's Rakos*, supra, 53 F. Supp. at pages 758-759.]

(b) *Testimony of Experts as to Consensus of Scientific Opinion Is Also Relevant*

"Dr. James M. Dille, professor of pharmacology and assistant dean of the School of Medicine of the University of Washington, while on the witness stand went down the list of ingredients of Nue-Ovo and categorically reported that scientific 'investigation' by 'doctors or pharmacologists' has shown that many of the ingredients have no 'action' as drugs. For example concerning plume thistle, the first ingredient listed in the statement of 'agreed facts', Dr. Dille said:

It has no action that doctors or pharmacologists can find, at all.

"Again, as to ginseng, another Nue-Ovo ingredient, Dr. Dille said:

. . . as modern pharmacology developed and they made all sorts of investigations on ginseng, they found that it is absolutely without any potent principal (principle?) of any value to medicine.

"It is generally agreed that testimony as to the consensus of medical opinion may be considered in drug-misbranding cases. In *United States v. Dr. David Roberts Veterinary Co.* (CCA 7), 104 F. 2d 785, 788, the court said:

In support of this count the testimony disclosed that the product does not contain ingredients which would be effective as a treatment for shoeboils or poll evil; that it has no value in the treatment of enlarged glands; and that no drug or mixture of drugs is known to the profession generally, or agreed upon by the consensus of veterinary opinion, that can do all of the things claimed by this label.

The record also discloses that the professional witnesses for the government testified that the opinions expressed by them were in accord with the consensus of medical opinion. * * *

In the instant case, the question was reduced to one of fact, as distinguished from mere opinion, [cases cited], and, as defendants' testimony made for conflicting evidence, a question of weighing the evidence was presented. To weigh the evidence is not within the power of this court. [See also 28 C. J. S. Druggists § 12 k (2), page 531.]

(c) *Even Opinion Testimony as to Therapeutic Value is Admissible*

"In this circuit and elsewhere, it has been held that expert testimony even in its broadest sense—i. e., where the witness has neither tested the product nor purports to report the consensus of medical opinion—is admissible on the question of therapeutic value.

"In *John J. Fulton Co. v. Federal Trade Commission* (CCA 9), 130 F. 2d 85, 86, certiorari denied, 317 U. S. 679, we said:

The findings have support in the testimony of expert witnesses called by the Commission. But the petitioner argues that since none of the experts had prescribed Uvursin or observed its effects in concrete cases their testimony was incompetent and inadmissible. We think otherwise. The witnesses were shown to possess wide knowledge in the field under inquiry. There is no reason to suppose them incompetent to express an opinion as to the lack of therapeutic value of petitioner's preparation merely because they had had no personal experience with it in the treatment of the disease. Their general medical and pharmacological knowledge qualified them to testify. [Cases cited.]¹

"The same doctrine has been followed in misbranding cases tried before juries. In *Goodwin v. United States* (CCA 6), 2 F. 2d 200, 201, cited by us with approval in the *Fulton* case, supra, it was said:

Upon the trial of the issue of fact joined by the libel charging the misbranding of mineral water and the answer of the intervenor, expert evidence may be properly admitted. If it appears from the testimony of a witness upon preliminary examination that he is learned in the science of chemistry or has been regularly and legally admitted to the practice of medicine, and that he has knowledge of the drug elements contained in the article transported in . . . interstate commerce and their efficacy or lack of efficacy as curative agents, used either separately or in combination in the treatment of the diseases specified on the label, his opinion on that subject is competent evidence regardless of whether he has had actual experience or observation of the effect of the use of such drugs in the exact form in which they are transported in interstate commerce. *The weight of his evidence is a question for the jury.* [Emphasis supplied.]²

The evidence in this case included the three types that we have discussed hereinabove: Testimony by experts based on (a) tests made of the product itself; (b) the consensus of medical opinion as to the various ingredients used in Nue-Ovo; and (c) the expert witnesses' personal opinions regarding the effectiveness of such ingredients. Altogether, there was ample evidence to support the verdict of the jury.

3. *Much of the Factual Evidence of the Appellee Consisted of Other Than Medical Testimony*

"It will be remembered that in the *Eckman's* Alternative case, supra, Mr. Justice Hughes has pointed out that Congress has 'recognized that there was a wide field in which assertions as to curative effect are in no sense honest expressions of opinion but constitute absolute falsehoods.' In the instant case, the appellee presented factual evidence of definite untruths and half-truths contained in the labeling of Nue-Ovo. This evidence did not come from medical experts but from documents and from lay witnesses.

"The labeling purports to quote from a letter written by Mrs. Fred Anderson, of Albany, Oregon, in part as follows:

I wish to say that after taking Nue-Ovo I feel like a new person, inasmuch as my nerves are 100% better—no trace of Neuritis left and a general built-up condition.

"This letter is one of a group that appears on the labeling, with the following notation: 'Original letters on file in office. Copies may be obtained on request.'

"In a 'motion to produce documents,' the appellee demanded that the originals of a number of these letters be produced by the appellant, including the letter attributed to Mrs. Anderson.

"Mrs. Eleanor M. Feldman, president of the appellant, was unable to produce the originals of at least four of the letters, including that of Mrs. Anderson. Instead, 'copies' were offered. Mrs. Feldman explained that in moving from

¹ See also *Irwin v. Fed. Trade Comm.* (CCA 8), 143 F. 2d 316, 324; *Charles of the Ritz Distributors Corp. v. Fed. Trade Comm.* (CCA 2), 143 F. 2d, 676, 678-679.

² See also 28 C. J. S. id.

one location to another, some of the appellant's documents were lost, an entire steel file having disappeared from her office.

"Mrs. Anderson gave a deposition in which she stated that after taking the first three or four bottles of Nue-Ovo she thought that her 'time had come'; that she didn't think it had done her any good; that she did not have neuritis, but arthritis; that she did not write the letter, and could not account for it; 'How on earth they got my name is more than I know.' A former employee of the appellant asked Mrs. Anderson to give him a testimonial, but she refused, according to her deposition.

"Another part of the Nue-Ovo labeling contains two 'before-and-after' photographs of H. J. Shermer of Leaburg, Oregon, flanking the facsimile of a notarized letter by him extolling the merits of that nostrum. The photograph taken 'before' Nue-Ovo shows Mr. Shermer in an emaciated condition, his weight being given as 110 pounds. The post-Nue-Ovo photograph shows Mr. Shermer as he appeared eighteen months later, weighing 165 pounds.

"In his letter, Mr. Shermer stated that he was first afflicted with arthritis fifteen years prior to the date of writing, October 8, 1934. After taking Nue-Ovo for 18 months, Mr. Shermer wrote, he was able to attend to his business, pursue his hobbies of hunting and fishing, 'and enjoy life generally.'

"C. W. Frazier, of Newburg, Oregon, who had been for sixteen years the sheriff of Harney County, Oregon, himself a sufferer from arthritis or rheumatism, or possibly both, saw the photographs and the facsimile letter of Mr. Shermer. With the traditional skepticism of a peace officer, the former sheriff decided to investigate. He called upon Mr. Shermer and found him sitting by a trailer, with his feet on a padded stool and a pair of crutches at his side.

"Mr. Frazier wrote to the appellant about his 'disappointing visit' to Mr. Shermer. In reply, Mrs. Feldman 'explained' that the 'back-set' was due to the complete extraction of Mr. Shermer's teeth at one time and to overwork. Mrs. Feldman further wrote that Nue-Ovo was helping Mr. Shermer 'for the third time,' and she felt certain 'that now that he is free of responsibility and that he and Mrs. Shermer can have a little more leisure time, he will make his third recovery.'

"Still not satisfied with the outcome of the Shermer investigation, Mr. Frazier called upon Mrs. Feldman in person. Mr. Frazier testified:

Well, the conversation got a little exciting a time or two. Mrs. Feldman sort of accused me of trying to make her out one damn liar, so she said. Why I told her, I said "Mrs. Feldman, I wouldn't think of putting it that way," but I said "Your advertising I still question quite a little."

"Finally, the Nue-Ovo labeling contains an 'analysis of ingredients,' with the prefatory explanation that it is based chiefly on the United States Dispensatory, the Pharmacopoeia, and various textbooks on pharmacology.

"It is here that half-truths enter the picture. While the label's 'analysis' followed part of the language of the above-named authorities somewhat closely and sometimes verbatim, there were significant omissions in the excerpts. Here are a few of the deleted portions:

(Ginseng) The extraordinary medicinal virtues formerly described as [ascribed to] Ginseng had no other existence than in the imagination of the Chinese.

(Horehound) It has, however, been almost completely abandoned by physicians.

(Salvia or sage) For what reason this condiment was admitted into the N. F. is not obvious. While the ancients say it is highly esteemed, there is no evidence that it possesses therapeutic virtues, and it is practically never prescribed by physicians.

(Lappa or Burdock) There is not sufficient reason, however, to believe it has any medicinal virtues.

"The apocryphal or misleading testimonials and the scientific half-truths in the labeling alone make out a case of actionable misbranding. As was said by the Supreme Court in *Donaldson v. Read Magazine*, Slip Opinion, page 10, decided on March 8, 1948:

Advertisements as a whole may be completely misleading although every sentence separately considered is literally true. This may be because things are omitted that should be said, . . .

As we shall see hereafter, this doctrine is specifically incorporated in the statute now under consideration. See 21 USCA § 321 (n), *infra*.

4. *There Was No Error in the Admission of Evidence of Misleading Material Not part of the Labeling*

"The appellant complains that the appellee sought to show that its 'lay witnesses' had been misled by material that was not part of the labeling seized.

Particular criticism is directed against the questioning of 'witness after witness' regarding a newspaper advertisement in which Anna Pautz invited persons suffering from arthritis, neuritis, rheumatism, sciatica and lumbago to communicate with her; and also regarding a letter in her handwriting and with her signature, stating that she had been benefited by using Nue-Ovo. The appellant concedes that the testimony showed that the letter in each instance that it was sent out had not been written personally by Mrs. Pautz, but was the reproduction of a letter originally written and signed by her.

"To say that the appellant did not deal frankly with the public in connection with the Pautz letter would be a distinct understatement. Further details are necessary to bring out the complete shadiness of this publicity project, which in the oral argument counsel for the appellant declined to defend.

"Mrs. Pautz, who was 76 years old at the time she testified, became a stockholder in the appellant about 1924, before using Nue-Ovo for arthritis. She testified that it cured her. She has never taken Nue-Ovo since 1923 or 1924.

"Beginning in 1945, there appeared in Portland newspapers, and later in other publications in the United States the following advertisement:

Rheumatism and Arthritis

I suffered for years and am so thankful that I am free from pain and able to do my work that I will gladly answer any one writing me for information. Mrs. Anna Pautz, P. O. Box 825, Vancouver, Wash.

Ed. Adv. Nue-Ovo Laboratories, 403 N. W. 9th Ave., Portland 9, Ore.

"At first, Mrs. Pautz financed the running of the advertisement and the rental of the post office box out of her own funds. Later, however, according to Mrs. Feldman's testimony, the appellant apparently took over the advertising costs, through a block advertising agency:

Mrs. Pautz is quite an old lady, and a very sweet old soul. When I found she was running it, I certainly wouldn't permit her to pay for it.

"A month or two after the advertisement first appeared, in a Portland newspaper, Mrs. Pautz composed and wrote out the letter in question, no one helping her with it. Her motive for doing so was just because she 'wanted to help somebody.'

"The letter contained the salutation 'Dear Friend,' and advised sufferers from arthritis and rheumatism to visit or write to the appellant's headquarters. In the letter Mrs. Pautz gave the Vancouver post office box as her mail address.

"Mrs. Pautz testified that at the time she wrote the letter, she did not own any stock in the appellant, having sold her shares to one of her sisters.

"Mrs. Pautz actually lives in Portland, which has been her home for fifty-eight years. The evidence adduced by the appellant as to why Mrs. Pautz gave the Vancouver address is contradictory. Mrs. Pautz herself testified that she never used the Vancouver box for her personal mail and that Vancouver was selected—

Because there is a girl working in the laboratories at Vancouver, Washington, and she could pick up the mail and bring it to the laboratories.

"Mrs. Feldman gave a different explanation of the Vancouver arrangements. She testified that the appellant has a contract with a *transfer company* to pick up the mail from the Vancouver box and take it to Portland, where, as we have seen, both Mrs. Pautz and the appellant have their domiciles. The replies to the letters thus received are then carted back to Vancouver and mailed there, by 'that same man that brings the letters.'

"When she was asked why this roundabout way of handling Mrs. Pautz' mail is employed, Mrs. Feldman repeatedly gave this cryptic reply:

Because it is convenient.

"The handwritten letter of Mrs. Pautz was mimeographed and sent out directly from the appellant's laboratories without any notation or other disclosure to the addressee that it is being sent from the appellant's headquarters, or that the appellant has had it mimeographed. The envelopes in which the Pautz letters are sent out are addressed in handwriting, although all the other correspondence of the appellant goes out in typed envelopes.

"The evidence on this point makes it quite clear that it was the appellant's intention to have the recipients of the Pautz letters believe that Mrs. Pautz herself had written each individual letter and had mailed it at Vancouver.

"After Mrs. Pautz's letter was sent out, the office of the appellant customarily mailed to those answering her advertisement a letter in which it was stated

that Mr. and Mrs. Pautz usually have some Nue-Ovo 'on hand and take it for a time every Spring as more or less of general tonic.' This statement is in direct contradiction to Mrs. Pautz's testimony that she had not used Nue-Ovo since 1923 or 1924.

"Both sides agree that 'the question of good faith and the question of intent is not involved' in this case; that 'the Government does not have to show a fraudulent intent on the part of the shipper or manufacturer'; and that, 'conversely, if it is shown that the product proceeded against is adulterated or misbranded, then good faith or a lawful intent will not constitute a defense.'

"Prior to 1938, when the present Food, Drug, and Cosmetic law was enacted, the statute *did* provide that an untrue statement in the labeling of a drug product had to be 'false and fraudulent' in order to render the product subject to condemnation for misbranding. Section 10 of the 1927 edition of 21 USCA read in part as follows:

§ 10 *Misbranded articles.* For the purpose of sections 1 to 15, inclusive, of this title, an article shall be deemed to be misbranded;

Drugs. In case of drugs.

False statement of curative or therapeutic effect.—Third. If its package or label shall bear or contain any statement, design, or device regarding the curative or therapeutic effect of such article or any of the ingredients or substances contained therein, which is false and fraudulent. [Emphasis supplied.]

"The present law requires only that the labeling be 'false or misleading in any particular' in order to bring the drug within the definition of 'misbranded.' 21 USCA 352 (a).

"This does not mean, however, that under the present law the appellee, in presenting to the jury a fair and complete picture of the claimant's activities, must sedulously avoid adducing any evidence of fraud. As the appellee points out—

In the instant case, the jury had the right to know that whatever propensity the purchasers of Nue-Ovo might have had to analyze had been reduced to a minimum by the groundwork laid by Appellant. In determining whether the labeling suggests to the user that Nue-Ovo is effective in the treatment of arthritis, rheumatism, neuritis, sciatica, and lumbago, we submit that it was proper for the jury to consider the labeling representations in the light of the setting in which the manufacturer intended the user to read them.

"It is well settled that the 1938 act was intended to make the provisions against misbranding stricter and not more lenient than they had been in pre-existing laws. The new statute was not designed to provide the misbrander of drugs with additional technical loopholes for escape, but to batten down those already existing.

"The evidence of the Congressional intent, as construed by the Supreme Court of the United States, is impressive. In *United States v. Dotterweich*, 320 U. S. 277, 280-282, the court said:

The Food and Drugs Act of 1906 was an exertion by Congress of its power to keep impure and adulterated food and drugs out of the channels of commerce. By the Act of 1938, Congress extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience. The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. [Cases cited] The prosecution to which *Dotterweich* was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger. [Case cited] And so it is clear that shipments like those now in issue are "punished by the statute if the article is misbranded [or adulterated], and that the article may be misbranded [or adulterated] without any conscious fraud at all. It was natural enough to throw this risk on shippers with regard to the identity of their wares. . . ." *United States v. Johnson*, 221 U. S. 483, 497-98.

* * * Nothing is clearer than that the later legislation was designed to enlarge and stiffen the penal net and not to narrow and loosen it. This purpose was unequivocally avowed by the two committees which reported the bills to the Congress. The House Committee reported that the Act "seeks to set up effective provisions against abuses of consumer welfare growing out of inadequacies in the Food and Drugs Act of June 30, 1906." (H. Rep. No. 2139, 75th Cong., 3d Sess., p. 1.) And the Senate Committee explicitly pointed out that the new legislation "must not weaken the existing laws," but on the contrary "it must strengthen and extend that law's protection of the consumer." (S. Rep. No. 152, 75th Cong., 1st Sess., p. 1)

"Furthermore, the Act is remedial, and should be liberally construed so as to carry out its beneficent purposes. In *United States v. 95 Barrels of Vinegar*, 265 U. S. 438, 442-443, the court said:

The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. *Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false.* It is not difficult to choose statements, designs and devices which will not deceive. *Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the Act.* [Emphasis supplied.]³

"We do not think that we would be construing the statute in accordance with the Congressional purposes if we were to hold that it was reversible error for the appellee to be allowed to introduce evidence regarding the 'indirection' employed by the appellant in connection with the shuttling of the Pautz mail back and forth between Vancouver and Portland, Oregon. One would have to be quite naive not to discern in this subterfuge, the thinly disguised purpose of causing the public to believe that there was no connection between the appellant and Mrs. Pautz.

"It is true that the letter was not part of the labeling. It was, however, part and parcel of the appellant's questionable promotional methods, some of which were reflected in the labels, as was amply disclosed by the evidence to which we have referred in the preceding section. It was not error for the court below to permit the appellee to lay before the jury the entire picture.

5. *There Was No Error in the Instruction Regarding the Test to Be Applied in Determining Whether the Labeling Is Misleading*

"The appellant complains that the 'error' in the admission in evidence of the Pautz letter and advertisement, supra, was 'compounded' when the court instructed the jury on 21 USCA § 321 (n). That subsection reads as follows:

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

"The objection is not that the instruction as to this subsection was erroneous per se, but that the error lay in giving *any* instruction as to that provision of the statute. The appellant contends that 'the instant libels make no general charge of misbranding under which the appellee is entitled to rely upon Section 201 (n) of the Act, [21 USCA § 321 (n)] supra,' but that the present charge is 'merely that the product is not effective.' 'Certainly,' it is argued, 'no reference to Section 201 (n) appears in any of the pleadings or the pretrial order,' etc.

"In making this attack upon the court's instruction as to the subsection in question, the appellant seems to forget the half-truths in the labeling to which we have referred in a preceding section herein. It will be remembered that, though the appellant announced in its label that its 'analysis of Ingredients' was based chiefly on the United States Dispensatory, the Pharmacopoeia, and various textbooks, and although it did indeed quote verbatim from some of these authorities, it unfairly omitted unfavorable comments regarding some of Nue-Ovo's ingredients.

"It was to cover precisely such tricky omissions and suppressions that Section 321 (n) was designed.

"Furthermore, in *any* case where 'an article is alleged to be misbranded because the labeling is misleading' in *any* respect, it is made mandatory by § 321 (n) itself that the jury 'shall' take into account such omissions or suppressions. In the instant case, the third agreed issue in the pretrial order was 'Whether or not the product is misbranded by reason of the labeling.' In the libels themselves, it is set forth that the article 'was misbranded . . . in that the statements . . . which appear in the labeling . . . are false and misleading in this,' etc.

³ See also *U. S. v. Dotterweich*, supra, 320 U. S. at page 282; *U. S. v. Antikamnia Co.*, 231 U. S. 654, 667; *U. S. v. John J. Fulton Co.* (CCA 9), 33 F. 2d 506, 507; *U. S. v. 62 packages, more or less, of Marmola Prescription Tablets* (DC Wis.), 48 F. Supp. 878, 887, affirmed, 142 F. 2d 107, certiorari denied, 323 U. S. 731-732; 50 Am. Jur., Statutes, § 395, page 420.

"Accordingly, it was not only not erroneous for the court to instruct the jury on § 321 (n), but, under the facts of this case and under the terms of the subsection itself, it was the court's duty to do so.

6. The Court Did Not Abuse Its Discretion in Refusing to Release the Product under Bond

"Finally, the appellant asserts that, even if this court should hold 'that the verdict may be construed as finding merely mislabeling consisting of the failure to disclose the difference of opinion among the experts,' etc, then 'fairness to appellant requires the release of the product under bond to permit amendment of the labeling and the [lower] court's denial of appellant's motion for that relief is an abuse of discretion,' etc.

"As we have tried to show, however, the appellee's evidence was not confined to 'opinion among the experts,' but was definitely *factual*.

"In denying the application for the release of Nue-Ovo under bond, the court below said:

... [Nue-Ovo] hasn't any intrinsic value for food or for uses other than a medicinal use. The jury has determined that it hasn't any value for that purpose, so it would be inconsistent, it seems to me, for me to hold that it should be preserved and released to the claimant.

"It is well settled that the trial court, in a case of this kind, shall exercise its sound discretion as to whether the article shall be released under bond. *United States v. Two Cans of Oil of Sweet Birch, etc.* (DC N. Y.), 268 F. 866, 867; *United States v. 143 Packages, etc., of Nue-Ovo* (DC Wash.), 51 F. Supp. 1, 2; *United States v. 1322 Cans More or Less, of Black Raspberry Puree* (DC Ohio), 68 F Supp. 881, 882.

"After careful consideration of the 1100-page record in this case, we are convinced that the court below exercised its discretion soundly and judiciously. We believe that the interests of the public will be better subserved by having this product kept off of the market altogether.

"The judgments are affirmed."

A petition for certiorari was filed on July 1, 1948, in the United States Supreme Court on behalf of the claimant, but was denied on October 18, 1948. On February 14, 1949, an order was entered directing that the product and the printed matter be destroyed.

2922. Misbranding of Colusa Natural Oil and Colusa Natural Oil Capsules. U. S. v. 9 Bottles, etc. (and 5 other seizure actions). Tried to the court; judgment for the Government. Decree of condemnation and destruction. Judgment affirmed upon appeal. Petition for writ of certiorari denied by U. S. Supreme Court. (F. D. C. Nos. 23160, 23197, 23200, 23493, 23512, 23548. Sample Nos. 39279-H, 39280-H, 39289-H, 39290-H, 79506-H, 79507-H, 86499-H, 86500-H, 86909-H, 86910-H, 87072-H, 87073-H.)

LIBELS FILED: Between June 2 and August 4, 1947, Northern District of Iowa, District of Colorado, and Eastern District of Wisconsin.

ALLEGED SHIPMENT: Between the approximate dates of April 1 and July 9, 1947, by the Colusa Remedy Co., from Chicago, Ill., and Los Angeles and Hollywood, Calif.

PRODUCT: 129 2-ounce bottles and 38 4-ounce bottles of *Colusa Natural Oil* and 135 100-capsule bottles and 39 200-capsule bottles of *Colusa Natural Oil Capsules* at Waterloo and Fort Dodge, Iowa; Colorado Springs, Colo.; and Green Bay, Racine, and Appleton, Wis. Examination disclosed that the products consisted of crude petroleum oil.

LABEL, IN PART: "Colusa Natural Oil."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle labels were false and misleading. These statements represented and suggested that the articles, when taken individually or in combination, were

effective in the treatment of psoriasis, eczema, leg ulcers, athlete's foot, and open sores, whereas the articles when taken as directed were not effective for such purposes.

DISPOSITION: The cases were consolidated for trial in the Northern District of Iowa, and answers were filed by the Colusa Remedy Co., claimant, denying that the products were misbranded.

The trial commenced on November 13, 1947, and was concluded on November 18, 1947. On November 26, 1947, the court handed down its findings of fact and conclusions of law and, in accordance therewith, entered a decree providing for the condemnation and destruction of the products.

The matter was appealed to the United States Court of Appeals for the Eighth Circuit, and on July 28, 1949, after consideration of the briefs and arguments of counsel, the following opinion was handed down, affirming the judgment of the district court:

THOMAS, Circuit Judge: "This is an appeal by the claimant from decrees entered under Section 304 of the Federal Food, Drug, and Cosmetic Act, 21 U. S. C. Section 334, condemning shipments in interstate commerce of certain drugs on the ground that they were misbranded within the meaning of Section 502 (a) of the Act, 21 U. S. C. Section 352 (a).

"Six libel proceedings were commenced by the government in three different jurisdictions to condemn six shipments in interstate commerce of Colusa Natural Oil and Colusa Natural Oil Capsules alleged to have been misbranded, and the proceedings were consolidated for trial in the Northern District of Iowa under the provisions of 21 U. S. C. Section 334 (b).

"The shipments involved were made in interstate commerce by the Colusa Remedy Company, a Nevada corporation, from Los Angeles, California, to the places and to the consignees named in each of the libels filed in each of the consolidated proceedings. The drug was bottled in two forms, capsule and liquid, it being stipulated that the contents in each case were identical, both containing 'natural unrefined petroleum oil.' It was further stipulated that the labels attached to the bottles in every case read:

[Colusa Natural Oil] A natural unrefined petroleum oil intended for use in treatment of Psoriasis, Eczema, Athlete's foot and Leg Ulcers. Directions: Apply to affected parts and rub it in thoroughly morning and night. For open sores saturate cotton pad with oil and bind on by gauze. Change to fresh dressing morning and night. For tender skin oil can be diluted 50% with olive oil. Continue treatment until skin is smooth and comfortable. We suggest in treatment of Psoriasis, Eczema and Leg Ulcers using Colusa Natural Oil externally as above directed and Colusa Natural Oil capsules internally as directed on bottle containing Colusa Natural Oil capsules.

[Colusa Natural Oil Capsules] A natural unrefined petroleum oil in capsules intended for internal use in treatment of Psoriasis, Eczema, Leg Ulcers. Directions: For adults start with one capsule at bedtime then after 3 days change to one capsule after each meal until skin is smooth and comfortable. For children under ten—one capsule or its contents squeezed into milk or water at bedtime until skin is smooth and comfortable. We suggest use of capsules as above directed in conjunction with liquid Colusa Natural Oil applied externally to affected parts as directed on bottle containing Colusa Natural Oil in liquid form.

"In each libel it was charged that such labels 'are false and misleading in that such statements represent and suggest that the articles when taken individually or in combination are effective in the treatment of psoriasis, eczema, leg ulcers, athlete's foot, and open sores, whereas, the articles when taken as directed are not effective for such purposes.'

"In each of the consolidated cases the appellant appeared as claimant and filed an answer, admitting the interstate shipments, the accuracy of the quoted labels, and denying that the articles were misbranded in interstate commerce within the meaning of the statute, or that the wording of the labels is false and misleading in the respects alleged, or that they were liable to seizure and condemnation pursuant to the provisions of the Act, and praying for the return of the articles and for such other relief as the case may require.

"The Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, 21 U. S. C. Section 301, et seq., provides:

[Section 201 (g), 21 U. S. C. 321 (g)] The term "drug" means . . . (2) articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals.

"Section 304 (a), 21 U. S. C. Section 334, provides that any drug that is misbranded when introduced into or while in interstate commerce, shall be liable to be proceeded against on libel of information in any district court within the jurisdiction of which the article is found.

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty.

When proceedings involving the same claimant and the same issues of misbranding are pending in two or more jurisdictions they may upon application of the claimant be consolidated for trial in any district selected by the claimant where one of the proceedings is pending.

[Section 502, 21 U. S. C. Section 352] A drug . . . shall be deemed to be misbranded—(a) if its labeling is false or misleading in any particular.

"The consolidated cases were tried to the court without a jury and thereafter the court made findings of fact, conclusions of law, and entered the decrees in each of the consolidated cases condemning the articles involved, from which decrees the claimant appeals. *United States v. 9 Bottles, More or Less, etc., Colusa Natural Oil, et al.*, 78 F. Supp. 721. And see *United States v. Colgrove, et al.*, S. D. Cal., 83 F. Supp. 880.

"Under the issues the burden was upon the government to establish that the labeling upon the bottles was false or misleading in some particular. That means in this case that the proof must warrant findings by the court (1) that Colusa Natural Oil and Colusa Natural Oil capsules are represented in the labeling to be effective or efficacious in the treatment of the skin diseases named in the labels and (2) that they are neither effective nor efficacious in the treatment of those diseases.

"Upon the trial the appellant contented that the labeling upon the articles involved is not 'false or misleading in any particular' within the meaning of 21 U. S. C. Section 352 (a). Its position was and is here that it does not claim in the labels or otherwise that Colusa Natural Oil will cure any of the diseases named in such labels. Its claim is that the labels represent only that the remedies will assist or relieve in the treatment of the diseases referred to in the labels.

"We think the law is settled both as to the issues and as to the review on appeal.

"A proceeding for forfeit and condemn property for violation of a federal statute but which does not involve the personal conviction of the wrong-doer for the offense charged is one of a civil nature and not criminal. *Dobbin's Distillery v. United States*, 96 U. S. 395, 399; *United States v. 935 Cases More or Less, Etc.*, 6 Cir., 136 F. 2d 523, 526.

"The provision of Section 304 (b) of the Federal Food, Drug, and Cosmetic Act, supra, that the procedure to seize misbranded drugs by libel should conform as nearly as may be to the procedure in admiralty was not intended 'to liken the proceedings to those in admiralty beyond the seizure of the property by process in rem, then giving the case the character of a law action. . . .' *445 Cases of Frozen Egg Product v. United States*, 226 U. S. 162, 183.

"The Federal Rules of Civil Procedure govern proceedings on appeals in actions for forfeiture of property for violation of a statute of the United States. Rule 81 (a) (2), 28 U. S. C. A. following Section 723c; *United States v. Cataldo*, 1 Cir., 157 F. 2d 803; *C. C. Co. v. United States*, 5 Cir., 147 F. 2d 820; *Reynal v. United States*, 5 Cir., 153 F. 2d 929; *United States v. 5 Cases, Etc.*, 9 F. R. D. 81.

"Since this is an action for the forfeiture of property for violation of a statute of the United States it is governed on appeal by Rule 52 (a) of the Rules of Civil Procedure, which provides that 'Findings of fact shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses.' In the notes to the rules prepared under the direction of the Advisory Committee on rules appointed by the Supreme Court it is said the foregoing rule 'accords with the decisions on the scope of the review in modern equity practice'; and 'It is applicable to all classes of findings in cases tried without a jury whether the finding is of a fact concerning which there was conflict of testimony, or of a fact deduced or inferred from uncontradicted testimony.' For a clear statement of the meaning of the rule the notes cite *Silver King Coalition Mines Co. v. Silver King Consolidated Mining Co.*, 8 Cir., 204 Fed. 166, 177, in which Judge Walter Sanborn, writing the opinion for the court, said: '. . . where a court has considered conflicting evidence, and made a finding or

decree, it is presumptively correct, and unless some obvious error of law has intervened, or some serious mistake of fact has been made, the findings or decree must be permitted to stand.' The rule has been repeated by the courts in cases too numerous to be cited. But see *Johnson v. Cooper*, 8 Cir., 172 F. 2d 937, and *Hudspeth v. Esso Standard Oil Co.*, 8 Cir., 170 F. 2d 418. The Supreme Court recently said in *United States v. U. S. Gypsum Co.*, 333 U. S. 364, 395, that a finding of fact is clearly erroneous when 'although there is evidence to support it, the reviewing court, on the entire evidence, is left with the definite and firm conviction that a mistake has been committed.'

"Upon the trial the government introduced the testimony of ten witnesses. The first three were agents and employees of the Federal Food and Drug Administration. They testified that they procured samples of Colusa Natural Oil and of the Colusa Natural Oil capsules and forwarded portions thereof to Dr. Hatch, Dr. Rosenberg, Dr. Carney, Dr. Trunnel, and Dr. Brewer. These doctors testified for the government; and it was agreed that the samples used by them in their tests and analyses were true samples of the drugs seized and condemned.

"Dr. Lewis F. Hatch of Austin, Texas, testified that he is Associate Professor of Chemistry at the University of Texas, and Research Chemist for the Defense Research Laboratory at the University of Texas. He had received degrees of Bachelor of Science in Chemistry, Master of Science in Chemistry and Doctor of Philosophy, specializing in chemistry. His work had been done on petroleum and its derivatives. He had published some 15 papers and pamphlets relating to the chemistry of petroleum and its derivatives. He had made several physical and chemical analyses of the samples furnished him of Colusa Natural Oil and of Colusa Natural Oil capsules and found them to be the same and apparently from the same source. He found that the material was essentially insoluble in water, was not radioactive, contained 0.2 of 1 per cent of nitrogen, 0.2 of 1 per cent of sulphur; its specific gravity was 0.924 at 24 degrees centigrade. It did not contain iodine, turpentine, camphor or ichthyl. He found no evidence of phenol, creosol or similar compounds. The material he found to be a natural petroleum oil. Ichthyl, he explained, is a manufactured product made from shale oil originating in Austria. He did not make a complete breakdown of all the elements of the samples. Such an examination would require many months.

"Dr. Irwin G. Gross, Ph. D., M. D., head of the Department of Pharmacology at the University of Iowa, testified that pharmacology is the study of drugs as to their chemistry, source, physical properties, preparation and physiological effects on living tissue, whether they be used in therapeutic amounts or otherwise, their absorption, their fats, their excretion and therapeutic indications for their use. In his opinion crude oil applied to the skin would act as an emollient; it would soften the skin, and act as an irritant to a slight extent. It would tend to block the hair follicles of the sebaceous glands and probably produce an infection of the plugged glands. In his opinion there is no pharmacological basis for the use of crude oil as beneficial action.

"Dr. Adolph Rostenberg, Jr., of Chicago, Illinois, is Associate Professor of Dermatology and Assistant Director of the Allergy unit of the University of Illinois, College of Medicine. He has been connected with other medical colleges and has had experience on the staffs of various hospitals. He is a member of the American Medical Association, of the Society for Investigative Dermatology, of the American Academy of Dermatology and Syphilology, and of the American Academy of Allergy. He testified that eczema is a response by the skin to a variety of stimulations; that the causes are various, such as poison ivy; and that in some instances crude petroleum oils are primary irritants. The treatments for eczema are various, depending upon the cause and the symptoms. In acute eczema oils should not be used because in some cases they are an irritant, and they should be used in no case because they tend to dam up the accretions of the skin and provide a good medium on which bacteria can flourish. Based upon his knowledge, training and experience in the field of dermatology crude petroleum oil applied either externally or internally is not an appropriate or effective treatment for all types of eczema, and that Colusa Natural Oil when used as directed on the label is neither an effective nor an appropriate treatment for all types of eczema. He had treated five patients, including himself, with Colusa Natural Oil and it effected no improvement in their cases. He expressed the same opinion as to the effectiveness of Colusa Natural Oil for the treatment of psoriasis, athlete's foot, and leg ulcers. It was his opinion that Colusa Natural Oil has no merit for the treatment of

any of those diseases. He observed that psoriasis is a recurring disease. It may get better for a short or indefinite period and then relapse again.

"Dr. Charles M. Brewer, Ph. D., a bacteriologist for the Food and Drug Administration, tested Colusa Natural Oil to determine whether it had any bactericidal or antifungicidal action, and found that it had none.

"Dr. Thomas L. Trunnell graduated from a four-year college course, after which he completed the course in medicine at the University of Iowa, followed by three years as an intern with training in dermatology. He practices dermatology at Waterloo, Iowa. Seven of his patients he treated with Colusa Natural Oil, two suffering from psoriasis. They became progressively worse and the treatment was stopped. Three were treated for eczema without results, and two for athlete's foot with no improvement. He expressed the opinion that Colusa Natural Oil has no merit for the treatment of any of those diseases.

"Dr. Robert G. Carney, Assistant Professor of Dermatology at the Iowa University Medical School at Iowa City, Iowa, spends 8 hours a day teaching students, treating patients, and carrying out research in dermatology. He is a member of several medical societies. In 1947 he treated patients in the University hospital with Colusa Natural Oil for eczema, stasis ulcer, psoriasis, and leg ulcers. He concluded that Colusa Natural Oil is neither an appropriate nor an effective treatment for any such diseases.

"The appellant's evidence consisted of the testimony of 30 witnesses: 14 lay-users of Colusa; 14 medical doctors by deposition; 1 medical doctor appeared in person; and a chemist referred to as Dr. Radovich.

"The lay witnesses testified that they had suffered from skin diseases (without naming them), describing the symptoms, their suffering; their treatment in most cases by doctors without practical results; and when at length they tried Colusa they received relief in every case; and in some cases they believed their ailment was cured.

"The medical doctors were general practitioners who treated skin diseases as well as ailments generally. Their testimony was that they had found Colusa Natural Oil and Colusa Natural Oil capsules both efficacious in the treatment of the four skin diseases named in the quoted labels; that it had in many cases effected permanent cures and had resulted in great relief in all cases.

"Dr. William T. Vincent of Houston, Texas, appeared at the trial and testified. He is 83 years of age and has practiced medicine since 1889. He studied at the Allopathic Medical College at Columbus, Ohio, and is a graduate of the University of Cincinnati. He testified that he had used Colusa Natural Oil in his practice for eight years; that he had treated hundreds of cases of skin diseases, including psoriasis, with good results; that he considers it an efficacious remedy, 'but not a cure all.'

"(Dr.) Frank O. Radovich of North Hollywood, California, is a chemist with a degree of Bachelor of Science and Applied Chemistry from the California Institute of Technology. His experience has been in the petroleum field entirely. He has been chemist for various petroleum refineries and has had charge of various testing laboratories; and he has done research work. He has produced a black viscous tarry material having the appearance of ichthyol from oils in the United States in and about California. He produced some of this material from Colusa Natural Oil in 1947. It was of the sulphur type. It does not, however, fulfill the specifications of the National Formulary. It would be possible, in his opinion, to manufacture ichthyol from Colusa crude oil.

"The first question for determination is whether the findings of the court that the labeling on each of the bottles containing Colusa Natural Oil in the liquid state or in capsules, when considered in its entirety, would be understood by a person of average intelligence who was suffering from one of the diseases referred to therein, and who was seeking a remedy for such disease as representing that if he would use Colusa Natural Oil as directed, that such oil would cure or alleviate such diseases of all types and kinds and at all stages thereof are 'clearly erroneous' within the meaning of those words as used in Rule 52 (a) of the Federal Rules of Civil Procedure, *supra*. After careful consideration of the entire record we think this finding of the court is not erroneous.

"In argument to the trial court counsel for appellant observed that 'The law with respect to the interpretation of such a label is this. The Court has the right to presume that purchasers are of average intelligence.' The court approved and applied this standard. Counsel for appellant continued, saying that 'The most that can be contended is that . . . there is an implied representation this (Colusa Natural Oil) would be of assistance, that it would be effica-

cious,' defining efficacy to mean to assist in the treatment of disease. We can find nothing in the label suggesting that Colusa Natural Oil is recommended as an auxiliary to some other remedy or that the purchaser should use it as an 'assistant' only in the cure or alleviation of any of the diseases named. The label reads:

A natural unrefined petroleum oil *for use in treatment of* [the named skin diseases] . . . Directions: Apply to affected parts . . . Continue treatment *until skin is smooth and comfortable* . . . [Italics supplied.]

Certainly the first quoted clause implies that the use of the oil as directed will be useful in some way and in some measure in the treatment of the named skin diseases. It could hardly be said to be a useful treatment if it will neither cure nor alleviate such diseases.

"The meaning and implications of the second quoted direction, 'Continue treatment until skin is smooth and comfortable,' are not explained by counsel. Certainly it implies that the 'smooth and comfortable' condition of the skin will be the result of the treatment, and that the Colusa Oil when used as directed is an effective agent which will produce such a result. It is true the words 'cure' or 'cured' are not used, but neither is the word 'assist.' If appellant had intended that persons afflicted with the named diseases would by the use of Colusa Oil as directed receive assistance only to endure their suffering it would have been easy to say so and thus avoid any ambiguity in the labeling. We think the interpretation of the labels by the trial court is reasonable and neither 'absurd' nor based upon 'a wholly distorted reasoning,' as suggested by appellant.

"Second, is the representation in the labeling that Colusa Natural Oil when used as directed 'will cure or alleviate' the named diseases 'false or misleading in any particular'?

"The evidence on this issue is conflicting. Based upon such evidence the court found that the labeling of the bottles seized in all the cases consolidated for trial is false and misleading in that there is no credible or adequate scientific or medical foundation for any claim or representation that Colusa Natural Oil when used externally or internally will cure or will alleviate the named skin diseases, or will give relief from such diseases or will assist in the treatment of them. The court heard all of the government's witnesses, all of appellant's lay witnesses and one of its doctors. Appellant's other evidence was in the form of depositions. So, giving due regard 'to the opportunity for the trial court to judge of the credibility of the witnesses' (Rule 52 (a)), we cannot say that this finding is clearly erroneous.

"But says the appellant in its printed brief the findings of the court are unsound and indefensible; that the great weight of the evidence is contrary to the findings. We did not see and hear the witnesses testify, of course, and we cannot be guided by the opinions of counsel. We may consider only their reasoning supported by applicable authorities to determine whether the court's findings are clearly erroneous.

"In its written brief counsel for appellant asserts that 'There is no allegation (in the libels) that the labels in question were on the Colusa bottles when they were shipped in interstate commerce.' This point was not suggested in the trial court. On the other hand it admitted in its answer the allegations of paragraphs 2 and 3 of the libel of information wherein the government alleged:

2. . . . that Colusa Remedy Company *shipped in interstate commerce* from Los Angeles, California, to Waterloo, Iowa, . . . 9 bottles . . . each containing 4 fluid ounces of an article *labeled in part* 'Colusa Natural Oil', and 13 bottles . . . each containing 100 capsules and 7 bottles . . . each containing 200 capsules of an article *labeled in part* 'Colusa Natural Oil' . . . in capsules intended for internal use.' 3. *That the aforesaid articles were misbranded in interstate commerce . . . in that the following statements which appear in the labeling of the articles, namely, [quoting the entire labels] . . . are false and misleading. . . . [Italics supplied.]*

These allegations cannot be reasonably or fairly construed to mean anything other than that the labels were on the bottles in which the 'article,' liquid oil, was contained at the time they were in interstate commerce.

"In discussing the weight of the evidence appellant in its brief contends that the Act does not apply to the situation presented here because its testimony demonstrated the merit and efficacy of Colusa Natural Oil, leaving nothing in dispute except the 'medical opinion' of the doctors; that putting aside the factual proof of appellant nothing more 'is involved than mere difference of opinion between schools of practitioners,' citing *United States v. 7 Jugs, Etc.*, D. C. Minn., 53 F. Supp. 746, and that 'the evidence is such that it appears that

the question of effectiveness has not transcended the realm of opinion into the realm of demonstrable fact.'

"It is true, as said by appellant in its brief, that 'The facts as to the history and development of the Food and Drug legislation, and the restrictions and limitations which Congress intended in connection therewith, are clearly reviewed in *U. S. v. 7 Jugs, Etc.*,' by Judge Joyce, but that review does not aid appellant on the point urged here. There is not presented here a mere difference of opinion between two schools of doctors. The question of whether the labeling on a drug 'is false and misleading in any particular' is a question of fact, and the test to be applied is whether the drug is effective in curing, or in giving relief from, the disease for which it is recommended. Upon this question the witnesses for the government made tests of the remedies, analyzed the product, and in some cases administered it to their patients. Their testimony was based upon such scientific knowledge so acquired. The question was, therefore, one of fact for the trial court to decide in the first instance.

"We have considered every contention presented by appellant in its brief. Minor contentions not discussed above are without merit and do not warrant any additions to the foregoing opinion."

A petition for a writ of certiorari was subsequently filed on behalf of the claimant, with the U. S. Supreme Court, and on January 9, 1950, the petition was denied.

2923. Misbranding of Nature's Minerals. *U. S. v. Nature's Mineral Food Co., Perry B. Smith, and Thornton B. Smith.* Pleas of not guilty. Tried to the court and jury. Verdict of guilty against company; verdicts of not guilty against individuals. Fine of \$500 against company. (F. D. C. No. 24263. Sample No. 73532-H.)

INDICTMENT RETURNED: On or about September 23, 1948, Southern District of Indiana, against the Nature's Mineral Food Co., a partnership, Indianapolis, Ind., and against Perry B. Smith and Thornton B. Smith, members of the partnership.

ALLEGED SHIPMENT: On or about June 6, 1947, from the State of Indiana into the State of Ohio.

LABEL, IN PART: (Bottle) "Nature's M. F. Co.'s Minerals 270 Tablets A Composition of Minerals Comprising Calcium Phosphate, Iodized Salt, Calcium Carbonate, Magnesium Sulphate (Epsom Salts), Sodium Phosphate, Sulphur Sublimed, Iron Sulphate and Potassium Iodide."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying printed cards entitled "Now a Mineral Health Resort in Your Home" were false and misleading since the article would not be efficacious in the treatment of the diseases, symptoms, and conditions represented, and the use of the article would not be effective to fulfill the promises of benefit stated and implied. The statements represented and suggested that the article would be efficacious in the treatment of acidosis, anemia, constipation, headache, lumbago, neuritis, rheumatism, sciatica, kidney and bladder disorders, nervousness, gastric ulcers, digestive troubles, sore muscles, impaired joint function, choking goiter, backache, gout, and skin eruptions; that use of the article would promote the flow of gastric juice, facilitate the digestion of food, restore health, build up atrophied tissues, give the user new ambition, prevent premature aging, and relieve pain; that use of the article would be equivalent to a sojourn at a resort in its effect on one's health; and that its use would result in vigorous health of the user.

DISPOSITION: Pleas of not guilty were filed on behalf of the individual defendants on October 1, 1948, and shortly thereafter a motion was filed to strike the alleged defendant, the Nature's Mineral Food Co., from the indictment since

the company as a partnership was not a legal entity. The court denied such motion; and on April 8, 1949, a plea of not guilty was entered for the company.

On May 6, 1949, the case came on for trial before a jury and lasted until May 7, 1949. The jury returned a verdict of guilty as to the company and a verdict of not guilty as to the individual defendants.

On May 11, 1949, defense counsel filed a motion in arrest of judgment on the basis (1) that a partnership in Indiana is not a legal entity and can not be guilty of a criminal offense; (2) that the punishment of the partnership after each partner had been acquitted would constitute double jeopardy; and (3) that the punishment of the partnership after each partner had been acquitted would deprive the partners of liberty or property without due process of law.

On July 5, 1949, the court overruled the motion in arrest of judgment, and on July 14, 1949, it assessed a fine of \$500 against the partnership.

2924. Misbranding of Gramer's Sulgly-Minol. U. S. v. 105 Bottles, etc. (F. D. C. No. 27234. Sample Nos. 41224-K, 41239-K.)

LIBEL FILED: June 7, 1949, Western District of Washington.

ALLEGED SHIPMENT: On or about May 16, 1949, by Walter W. Gramer, from Minneapolis, Minn. The circulars were shipped during the month of November 1948, and on or about March 31, 1949, and bore the titles "Arthritis It's Grip Broken," "A Light Should Not Be Hidden," and "An Additional Discovery."

PRODUCT: 105 4-ounce bottles of *Gramer's Sulgly-Minol* and 200 circulars at Seattle, Wash. Analysis showed that the product consisted essentially of a lime and sulfur solution with a small amount of glycerin.

LABEL, IN PART: "Gramer's Sulgly-Minol."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "For treatment of muscular pains, apply to soles of feet before retiring," which appeared on the bottle label, was false and misleading since the product when used as directed would not be effective in the treatment of muscular pains.

DISPOSITION: July 29, 1949. Default decree of condemnation and destruction.

2925. Misbranding of viscysate tablets and viscysate liquid. U. S. v. 36 Bottles, etc. (F. D. C. No. 27776. Sample Nos. 13157-K, 13158-K.)

LIBEL FILED: August 16, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 10, February 21, March 29, May 16, and July 11, 1949, by Ernst Bischoff Co., Inc., from Ivoryton, Conn.

PRODUCT: 36 bottles of *viscysate tablets* and 30 bottles of *viscysate liquid* at Philadelphia, Pa.

LABEL, IN PART: "50 Tablets Viscysate * * * Each Tablet Contains: Viscum Album (Solid Extract) 0.30 Gm. (4¾ grs.)" and "30 cc. Viscysate * * * Contents: Viscum Album extract . . . 86% Ethyl Alcohol . . . 14%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the articles and in an accompanying leaflet entitled "Viscysate" were false and misleading. The statements represented and suggested that the articles were effective in the treatment of high blood pressure, vasomotor disturbances caused by excitement, overexertion, climacteric manifestations,

cardiac and renal insufficiencies, headache, tinnitus aurium, and vertigo. The articles were not effective in the treatment of such conditions.

DISPOSITION: September 14, 1949. Default decree of condemnation and destruction.

2926. Misbranding of Aletris cordial and celerina. U. S. v. 69 Bottles, etc.
(F. D. C. No. 27300. Sample Nos. 55601-K, 55602-K.)

LIBEL FILED: June 6, 1949, Western District of Oklahoma.

ALLEGED SHIPMENT: On or about April 5, 1949, by the Rio Chemical Co., from New York, N. Y.

PRODUCT: 69 7-ounce bottles of *Aletris cordial* and *celerina* at Oklahoma City, Okla.

LABEL, IN PART: "Aletris Cordial A Compound Content of Alcohol 27.8 Per Cent * * * Formula: Each fluid ounce represents ten grains Aletris, thirty grains Helonias and thirty grains Scrophularia" and "Celerina Alcohol Forty-two Per Cent. Formula: Each fluid ounce represents forty grains each Kola and Crampbark; forty-eight grains Celery; Twenty grains Cypripedium; sixteen grains Xanthoxylum and Aromatics."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the labels of the articles were false and misleading since the articles were not effective in the treatment of the conditions referred to: (*Aletris cordial*) "For use in Functional Derangements of the Female Generative Organs" and (*celerina*) "For use in Functional Nervous Disorders."

DISPOSITION: July 27, 1949. Default decree of condemnation and destruction.

2927. Misbranding of Hemophoresis-Ionization Unit. U. S. v. 1 Device, etc.
(F. D. C. No. 28234. Sample No. 57811-K.)

LIBEL FILED: October 25, 1949, Southern District of California.

ALLEGED SHIPMENT: By D. P. Redding, from Kansas City, Mo. The device was shipped on or about March 16, 1949, and certain printed matter was shipped on or about January 8 and March 16, 1949.

PRODUCT: 1 *Hemophoresis-Ionization Unit*, a device, at Long Beach, Calif., together with a franchise agreement, a leaflet entitled "High Blood Pressure and Arthritic Case Reports," and a newspaper advertisement. The product was a device for converting the commercial electric current into a direct current of lower intensity. It was recommended for use in connection with a salt solution.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the franchise agreement, leaflet, and newspaper advertisement were false and misleading. These statements represented and suggested that the device was effective in relieving high blood pressure, arthritis, and heart disease; that it was effective in the removal of calcareous substance (lime) from the blood vessels; and that it would restore proper blood circulation to any diseased organ. The device was not effective for the purposes stated and implied.

DISPOSITION: November 28, 1949. Default decree of condemnation. The court ordered that the device and printed matter be delivered to the Food and Drug Administration, for experimental and exhibit purposes.

DRUGS FOR VETERINARY USE

2928. Misbranding of Liquid Hog Medicine. U. S. v. Roy L. Harris (R. L. Harris Co.). Plea of nolo contendere. Fine of \$50 plus costs. (F. D. C. No. 25622. Sample Nos. 51685-H, 25864-K.)

INFORMATION FILED: March 28, 1949, District of Nebraska, against Roy L. Harris, as a partner in the partnership of the R. L. Harris Co., and as an individual trading as the R. L. Harris Co., at Omaha, Nebr.

ALLEGED SHIPMENT: On or about October 12, 1946, and July 30, 1948, from the State of Nebraska into the States of South Dakota and Minnesota.

PRODUCT: Analysis showed that the product consisted of a solution containing sodium hydroxide, sodium carbonate, and sodium sulfate, with small amounts of strychnine, creosote, and guaiacol.

LABEL, IN PART: "Harris Blu-Rib-Un Liquid Hog Medicine."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. These statements represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of disease conditions of hogs, and in the cure, mitigation, and treatment of excess acid conditions in the stomach, intestinal infections, and diarrheas associated with hyperacidity in hogs. The article would not be efficacious for the purposes represented.

DISPOSITION: November 23, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$50, plus costs.

2929. Misbranding of Dia-Ton, Ry-Ton, Ton-It, and Kosa-Ton. U. S. v. 60 Bottles * * * (and 3 other seizure actions). (F. D. C. No. 27633. Sample Nos 43205-K to 43208-K, incl.)

LIBELS FILED: August 10, 1949, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about December 30, 1947, and February 16 and October 5, 1948, by Kilz-Jerm Laboratory, from Toledo, Ohio.

PRODUCT: 60 bottles of *Dia-Ton*, 12 bottles of *Ry-Ton*, 8 bottles of *Ton-It*, and 20 bottles of *Kosa-Ton* at Union City, Mich. The bottles were of various sizes, ranging from half-pint to half-gallon.

LABEL, IN PART: "Dia-Ton * * * Active Ingredients . . . 3.15% alkyl-dimethyl-benzyl-ammonium chloride," "Ry-Ton * * * Ingredients: Solution, 6.5% Potassium Bichromate, Cresote, N. F., Sodium Chloride (salt), .25% Potassium Iodide, Magnesium Sulphate (Epsom salts), Inert water," "Ton-It * * * Ingredients: Decoction of Digitalis, Ginger .65%, Nux Vomica 1.1%, (less than .01 grain Strychnine per ounce), Areca Nut 1.1%, Gentian 1.1%, Kamala, Capsicum, Anise Seed, American Worm Seed 1.1%, also Copper Sulphate, Iron Sulphate, Inert water, insoluble pulp removed," and *Kosa-Ton* * * * Ingredients: Solution Acetic Acid, Quebracho, Epsom Salt."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the labels of the articles were false and misleading since they represented and suggested that the articles were effective in the prevention and treatment of disease conditions and for the purposes mentioned, whereas the articles were not so effective: (Dia-Ton) "For Chickens For Turkeys * * * Baby Chicks, Baby Poults—Feed one tablespoon Dia-Ton to each gallon of all drinking water until chicks or poults are two weeks old. When pasting is present at any age, feed two tablespoons Dia-Ton to each gallon of all drinking water.

Feed until flock is normal. Grown Chickens, Turkeys—Dia-Ton may be fed one tablespoon to each gallon of drinking water as a precaution against the spread of disease * * * Rabbits—Feed one tablespoon Dia-Ton to each gallon of all drinking water. Use continuously. When disease is noticed, use two tablespoons of Dia-Ton to each gallon of drinking water. Calf—When calf shows symptoms of scours, feed three or four tablespoons of Dia-Ton in one pint of warm milk. Repeat treatment in six or eight hours if needed," (Ry-Ton) "to relieve symptoms of colds, roup, etc. * * * Baby Chicks Up To 4 Weeks Old—When no symptoms of disease are present, feed one tablespoon full Ry-Ton to each gallon of drinking water. Feed two or three days each week. When symptoms of disease are present, feed two tablespoons full of Ry-Ton to each gallon of drinking water until relief is apparent * * * Hens And Growing Birds—When no symptoms of disease are present, feed one to two tablespoons Ry-Ton to each gallon of drinking water every other day. When symptoms of disease are present, feed four tablespoons full of Ry-Ton to each gallon of drinking water until relief is apparent. If severe symptoms are present, dip heads of affected birds in warm water solution containing one tablespoon Ry-Ton to each quart of water. Ry-Ton can be fed in a wet mash when preferred," (Ton-It) "To relieve Symptoms of Round Worms * * * Chickens * * * For Chicks: * * * Rabbits: * * * Hogs," and (Kosa-Ton) "To relieve Symptoms of Coccidiosis Chickens * * * When Symptoms of Disease Is Present * * * Rabbits."

Further misbranding, Section 502 (e) (2), the *Ton-It* contained digitalis, and its label failed to declare the quantity or proportion of digitalis or digitalis glucosides contained therein.

DISPOSITION: September 13, 1949. Default decrees of condemnation and destruction.

2930. Misbranding *Ski Hi* (for dogs). U. S. v. 24 Bottles * * *. (F. D. C. No. 27620. Sample No. 63688-K.)

LABEL FILED: On or about August 18, 1949, Northern District of Georgia.

ALLEGED SHIPMENT: On or about May 24, 1949, by the Edisto Products Co., from Denmark, S. C.

PRODUCT: 24 half-ounce bottles of *Ski Hi* (for dogs) at La Fayette, Ga. Analysis showed that the product consisted essentially of a solution containing potassium iodide, iodine, and resorcinol, in a mixture of alcohol, glycerin, and water.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in a leaflet which was wrapped around the bottles of the article and which was entitled "*Ski Hi* An Important Announcement" were false and misleading: "The purpose of this little folder is to advise our many former customers and friends that because of a ruling of the Food and Drug Administration in Washington that *Ski Hi* was misbranded when sold as a remedy for Running Fits in dogs, it can no longer be sold as such. They base their ruling on the OPINION of veterinarians that it would not cure the disease, and regardless of the way we, or you may feel about it, we must abide by their ruling or be liable to criminal prosecution in the Federal Courts. However, we have gained permission from the Administration to sell it with a change in the label. The preparation as now labeled is identically the same as it always was. The directions are the same and inevitably the action the same. So, if you have used it for other ailments than the label now specifies, there is no control over your using it again for the same purpose. It is still a guaranteed remedy. It must satisfy." The above statements represented and suggested that the

article was effective in the treatment of running fits in dogs, whereas the article would not be effective for that purpose; and, further, the statements represented that the Food and Drug Administration had given permission to sell the article, whereas it had not given such permission.

DISPOSITION: September 14, 1949. Default decree of condemnation and destruction.

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¹ (2922) Seizure contested. Contains opinion of the court.

² (2923) Prosecution contested.

³ (2911) Seizure contested.

⁴ (2921) Seizure contested. Contains opinions of district court and court of appeals.

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Complex Capsules, Lack-		sules in Cold Pressed Wheat	
zoom's Garlic & Parsley Cap-		Germ Oil, Lackzoom Pure	
sules in Cold Pressed Wheat		Soybean Lecithin Capsules,	
Germ Oil, Lackzoom Pure		Wheat Germ Oil Capsules,	
Soybean Lecithin Capsules,		Amo-Tabs Amino Acid Tab-	
Wheat Germ Oil Capsules,		lets (Special Tablets), Lack-	
Amo-Tabs Amino Acid Tab-		zoom's "Supreme-A" Food	
lets (Special Tablets), Lack-		Supplement Capsules, Lack-	
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¹ (2922) Seizure contested. Contains opinion of the court.² (2923) Prosecution contested.³ (2911) Seizure contested.⁴ (2921) Seizure contested. Contains opinions of district court and court of appeals.

	N. J. No.		N. J. No.
Strong, Cobb & Co., Inc.:		Supplement Capsules, Lack-	
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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2931-2950

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

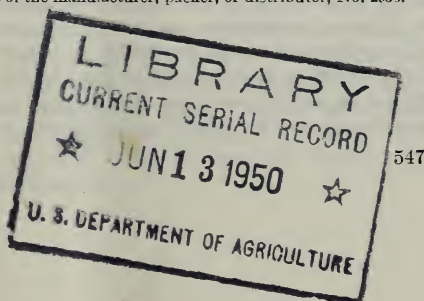
PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., May 19, 1950.

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*For omission of, or unsatisfactory, ingredients statements, see Nos. 2932, 2945; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 2932, 2936; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 2936.



**DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS****2931. Misbranding of male sex hormone tablets and female sex hormone tablets.**

U. S. v. Allen H. Parkinson (Hudson Products Co.). Plea of not guilty.
Tried to the court; verdict of guilty. Fine, \$400. (F. D. C. No. 26686.
Sample Nos. 6134-K, 14917-K, 37357-K, 37358-K.)

INFORMATION FILED: April 8, 1949, Southern District of California, against
Allen H. Parkinson, trading as the Hudson Products Co., Long Beach, Calif.

ALLEGED SHIPMENT: On or about February 27, June 15, and August 3, 1948,
from the State of California into the States of Pennsylvania; Illinois, and
Washington.

LABEL, IN PART: "Male Sex Hormones 10 Mg. Methyl-Testosterone Tablets" and
"Female Hormones 0.1 Mg. Cryst. a-Estradiol."

NATURE OF CHARGE: Male sex hormone tablets. Misbranding, Section 502 (a),
certain statements in accompanying leaflets entitled "The Male Hormone"
and "The Story of Hormones" were false and misleading. These statements
represented and suggested that the article was the true male sex hormone;
that in the average man in his late forties, it would stimulate growth and de-
velopment of the sex organs and the male sex characteristics, such as dis-
tribution of hair, muscular development, and depth of voice; that the article
would correct lack of sexual power and impotence; that it would relieve and
postpone the many conditions associated with middle age and would improve
the sense of well-being; that it would be efficacious in the treatment of flushes,
sweats, and chills, impaired memory, inability to concentrate on activities and
tendency to evade them, nervousness, depression, general weakness, and lack
of physical strength; that use of the article would result in improved physical
and mental work and would exert a tonic action resulting in renewed vigor;
that the article would impart a better attitude toward social life and would
cause nervousness, exhaustion, and melancholy to disappear; that in the aver-
age man, the article would relieve and postpone the many conditions formerly
thought to be inevitable with middle age; that it would be efficacious in the
treatment of nervous tension and intense subjective nervousness and irrita-
bility; that it would be efficacious in the treatment of numbness in the extremi-
ties, and itching, prickling, and tingling of the skin on waking up at night;
that it would be efficacious in the treatment of headaches; that it would
prevent a decrease in the ability to concentrate and would remedy faulty
memory; that it would be efficacious in the treatment of depression and
melancholia; that it would correct a lack of interest in social and business
life, lack of mental concentration, and lack of energy; that it would correct
a feeling of inadequacy and impotency; that it would be efficacious in the treat-
ment of hot flashes, feelings of smothering and sweating, and chilly, creepy
sensations; that it would prevent the user from tiring easily and gaining
excessive weight; that it would be efficacious in the treatment of constipation,
vague digestive complaints, and precordial angina pectoris-like pains; that it
would be efficacious in the treatment of urinary symptoms, such as frequency,
nocturia, dribbling, and inability to start urinary stream; that it would restore
confidence in mental reactions and decisions; that it would notably increase
the user's capacity for mental and physical work and that it would increase

potency and libido. The article was not the true male sex hormone, and it would not fulfill the promises of benefit stated and implied. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the following directions on the labeling of different portions of the article were not adequate directions for use: "Dosage: 1 tablet daily Important: In case of pronounced male sex hormone deficiency take 3 tablets daily for ten days. After 10 day period take 1 tablet daily" and "Dosage: 1 tablet daily Important: In case of pronounced male sex hormone deficiency take 3 tablets daily before eating for 10 days. After the 10 day period take 1 tablet daily before meals or as directed by your physician."

Female sex hormone tablets. Misbranding, Section 502 (a), certain statements in accompanying leaflets of the same titles as those referred to above were false and misleading. These statements represented and suggested that the article would relieve and postpone the conditions associated with middle age: that the article would bring prompt relief from hot flashes, emotional disturbances, and other manifestations associated with the menopause; and that it would be efficacious to bring about a steady readjustment and to help overcome most menopausal conditions in women approaching or passing through the menopause. The article would not be efficacious for the purposes represented. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions for use "Just One Tablet A Day" and "In case of pronounced female sex hormone deficiency take 3 tablets daily before meals for 10 days. After the 10 day period take 1 tablet daily or as directed by your physician," borne on the labeling of the article, were not adequate directions for use. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and duration of administration, in such manner and form as are necessary for the protection of users, since each tablet of the article contained .1 milligram of crystalline alpha estradiol; and the labeling of the article failed to warn that use of the article in the dosage and with the duration of administration recommended on its labeling may result in uterine bleeding and damage to the ovaries. Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling since each tablet contained .1 milligram of crystalline alpha estradiol, and the use of a drug containing .1 milligram of crystalline alpha estradiol with the frequency prescribed, recommended, and suggested in its labeling, namely, "3 tablets daily before meals for 10 days. After the 10-day period take 1 tablet daily," would be dangerous to health since use of the article may result in uterine bleeding and damage to the ovaries.

DISPOSITION: July 13, 1949. A plea of not guilty having been entered, the case came on for trial before the court without a jury. At the conclusion of the trial, the court returned a verdict of guilty and fined the defendant \$400.

2932. Misbranding of Male Hormone tablets, Menformon Dosules, Female tablets, and Metandren Linguets. U. S. v. El-O-Pathic Pharmacy, Inc., and Martin A. Clemens (as manager and director of the corporation and as an individual trading as M. A. Clemens Pharmacy). Pleas of not guilty. Tried to the court; verdict of guilty. Fine of \$700 against corporation and \$700 against Martin A. Clemens. (F. D. C. No. 25607. Sample Nos. 30046-K, 30047-K, 30068-K, 30919-K, 31204-K, 31208-K, 31217-K to 31220-K, incl., 31610-K.)

INFORMATION FILED: March 22, 1949, Southern District of California, against the El-O-Pathic Pharmacy, Inc., Los Angeles, Calif., and Martin A. Clemens, manager and director of the corporation and trading individually as the M. A. Clemens Pharmacy, Los Angeles, Calif.

ALLEGED VIOLATION: The El-O-Pathic Pharmacy, Inc., Los Angeles, Calif., and Martin A. Clemens, acting as manager and director of the El-O-Pathic Pharmacy, Inc., and trading individually as the M. A. Clemens Pharmacy, on or about October 26 and 30, November 1 and 6, and December 8 and 28, 1947, and January 9 and 19, 1948, caused the introduction into interstate commerce, at Los Angeles, Calif., for delivery to Tucson and Phoenix, Ariz., and Seattle, Wash., of quantities of products labeled *Male Hormone tablets*, *Female tablets*, *Menformon Dosules* and *Metandren Linguets*. When introduced into interstate commerce, the drugs were accompanied by circulars entitled "Male and Female Sex Hormones."

The defendants also made over-the-counter sales of three lots of the drug labeled *Male Hormone*. The drug had been shipped in interstate commerce from Nutley, Bloomfield, and Summit, N. J., to Los Angeles, Calif., and while held for sale after such shipment, it was repacked by the defendants into envelopes and sold to various persons without a physician's prescription, accompanied by circulars entitled "Male and Female Sex Hormones," which acts of the defendants resulted in the drug being misbranded.

LABEL, IN PART: (Male Hormone) "Each tablet contains 25 mg. [or "5 mg."] testosterone the form of the true male [all labels with one exception contained the word "sex"] hormone which is most highly effective for administration by mouth"; (Metandren Linguets) "Each linguet contains 5 mg. of Metandren (methyltestosterone), orally active androgen"; (Menformon Dosules) "(Female Sex Hormone Ointment in individual dose containers for accuracy of dosage). Each Dosule contains 1 gram of ointment. The active ingredient of Menformon Dosules is Non-Crystalline Estrone in natural combination with insignificant quantities of other naturally occurring female sex hormones (equilin and equilenin) derived from pregnant mare's urine. The content of estrogenic substance present in each dosule represents the estrus producing activity of 2000 International units of 0.2 mg. of standard crystalline keto-hydroxyestratriene (estrone)." The *Female tablets* bore no labeling on the box but the word "Female."

NATURE OF CHARGE: *Male Hormone tablets*. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. The statements represented and suggested that the article would stimulate growth and development of the sex organs, and the male sex characteristics such as distribution of hair, muscular development, and depth of voice; that it would correct lack of sexual power and impotence; that it would relieve and postpone the many conditions associated with middle age and would improve the sense of well-being; that it constituted an adequate treatment for flushes, sweats, chills, impaired memory, inability to concentrate on activities and tendency to evade them, nervousness, depression, general weakness, and lack of physical strength; that use of the article would result in improved physical and mental work and would exert a tonic action resulting in renewed vigor; and that the article would impart a better attitude toward social life and would cause nervousness, exhaustion, and melancholy to disappear in the average man in his late forties. The article would not constitute an adequate treatment for the conditions represented and would not fulfill the promises of

benefit stated and implied. Further misbranding, Section 502 (f) (2), the labeling of the four shipments of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, since each tablet contained 25 milligrams (or 5 milligrams) of male hormone (methyl testosterone); and the labeling of the four shipments failed to warn that use of the product may result in sterility and that its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth. Further misbranding, Section 502 (j), the article in all shipments and sales was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling since each tablet contained 25 milligrams (or 5 milligrams) of male hormone (methyl testosterone), and the use of an article containing 25 milligrams of male hormone in each tablet with the frequency prescribed, recommended, and suggested in the labeling, namely, as directed on some of the box labels, "1-2 tablets daily" or "2 tablets 3 times daily," and as directed in the circular "One tablet a day," would be dangerous to health in that such use of the article may result in sterility; and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

Menformon Dosules. Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. The statements represented and suggested that the article would be efficacious to develop the female breasts, and to stimulate mammary growth and result in definite breast growth of considerable degree, and that it would be efficacious in the treatment of underdeveloped breasts. The article would not be efficacious for such purposes.

Female tablets. Misbranding, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents; Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article; and, Section 502 (f) (1), the labeling of the article bore no directions for use. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health, in such manner and form as are necessary for the protection of users, since each tablet of the article contained 0.5 milligrams of alpha-estradiol; and the labeling of the article failed to warn that its unrestricted use may result in injury to the female generative system and that its use by females with early and incipient carcinoma of the breast, cervix, and uterus may result in acceleration of the malignant growth.

Metandren Linguets. Misbranding, Section 502 (a), the labeling of the article contained false and misleading statements of the same nature as the false and misleading statements described above, with respect to the *Male Hormone tablets*; Section 502 (f) (1), the labeling of the article bore no directions for use. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration, in such manner and form as are necessary for the protection of users, since each linguet of the article contained 5 milligrams of male hormone (methyl testosterone); and the labeling of the article failed to warn that its unrestricted use may result in sterility and that unrestricted use of the

article by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

DISPOSITION: Pleas of not guilty having been entered, the case came on for trial before the court without a jury on June 22, 1949. On July 13, 1949, the court returned a verdict of guilty on all counts as to both defendants and imposed a fine of \$700 against the corporation and \$700 against the individual.

2933. Misbranding of Metandren Linguets. U. S. v. George H. McKinlay (Health Chemicals). Plea of not guilty. Tried to the court. Verdict of guilty. Fine, \$300. (F. D. C. No. 25603. Sample Nos. 24585-K, 28038-K, 30045-K.)

INFORMATION FILED: March 28, 1949, Southern District of California, against George H. McKinlay, trading as Health Chemicals, Los Angeles, Calif.

ALLEGED SHIPMENT: On or about October 30, 1947, and April 1 and 26, 1948, from the State of California into the States of North Dakota, Colorado, and Arizona.

LABEL, IN PART: "Metandren Linguets * * * Compressed water especially designed for absorption from under the tongue or inside the cheek. Each linguet contains 5 mg. of Metandren (methyltestosterone), orally active androgen."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements relating to the article in an accompanying circular entitled "Hormones and the Male Climacteric" were false and misleading. The statements represented and suggested that the article would be an adequate treatment for headache, excessive fatigue, nervousness, irritability, insomnia, decreased memory and power of concentration, a feeling of uncertainty and tremulousness, vasomotor disturbances, such as flashes, sweats, chills, and paresthesias, vague pain, particularly in the region of the bladder, a loss of force in the urinary stream, clinical signs of prostatic hyperplasia or nonspecific prostatitis, decrease in libido and potency, symptoms of climacteric syndrome, and involutional melancholia; and that the article would prevent the "clock of life" from running down and would permit the user to resume with confidence normal business and social activities. The article would not be an adequate treatment for the conditions represented; it would not prevent the "clock of life" from running down; and it would not permit the user to resume with confidence normal business and social activities.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warning against use in those pathological conditions where its use may be dangerous to health and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, since each linguet of the article contained 5 milligrams of male hormone (methyl testosterone); and the labeling failed to warn that the use of the article may result in sterility and that its use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth. Further misbranding, Section 502 (j), the article was dangerous to health, when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, since each linguet of the article contained 5 milligrams of male hormone (methyl testosterone), and the use of a drug containing 5 milligrams of male hormone in each linguet with the frequency prescribed, recommended, and suggested in the labeling, namely, "3 to 4 Linguets per day," would be dangerous to health since use of the article may

result in sterility; and such use by individuals with early and incipient carcinoma of the prostate may result in acceleration of the malignant growth.

DISPOSITION: July 13, 1949. A plea of not guilty having been entered, the case came on for trial before the court without a jury. At the conclusion of the trial, the court returned a verdict of guilty and fined the defendant \$300.

2934. Misbranding of Foille Emulsion. U. S. v. 3 Bottles * * *. (F. D. C. No. 26973. Sample No. 23984-K.)

LABEL FILED: April 20, 1949, Western District of Louisiana.

ALLEGED SHIPMENT: On or about March 14, 1949, by the Carbisulphoil Co., from Dallas, Tex.

PRODUCT: 3 1-gallon bottles of *Foille Emulsion* at Ville Platte, La.

LABEL, IN PART: "Foille A Protective Dressing. Analgesic Antiseptic * * * Active Ingredients: Benzocaine, Carbolic Acid (Less than 2%), Calcium Oleate, Calcium and Potassium Iodides, Oxyquinoline Base, Calcium Thiosulfate and sulphur in a Vegetable Oil Base."

NATURE OF CHARGE: Misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe dosage and methods and duration of administration and application, in such manner and form, as are necessary for the protection of users, since the article contained carbolic acid; and its labeling failed to warn against application to large areas of the body, and against bandaging the fingers and toes to which the article was applied.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely (bottle label), "Apply liberally to gauze compress or directly to wound area."

DISPOSITION: January 9, 1950. Default decree of condemnation and destruction.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

2935. Misbranding of penicillin ointment and penicillin-G sodium crystalline, and adulteration and misbranding of Multovals Multi-Vitamins Gelucaps, Amberons Vitamin B Complex Gelucaps, and posterior pituitary ampuls. U. S. v. VCA Laboratories (Vitamin Corp. of America). Plea of guilty. Fine, \$3,300. (F. D. C. No. 26687. Sample Nos. 9437-K to 9439-K, incl., 9875-K, 10521-K, 10682-K.)

INFORMATION FILED: March 23, 1949, District of New Jersey, against the VCA Laboratories, a corporation, trading as the Vitamin Corp. of America, at Newark, N. J.

INTERSTATE SHIPMENT: On or about February 27, March 8 and 19, and July 1, 2, and 21, 1948, from the State of New Jersey into the State of New York.

LABEL, IN PART: "Harco * * * Penicillin Ointment * * * Harco Pharmaceutical Corp. Division of VCA Laboratories Newark, New Jersey," "Penicillin-G Sodium Crystalline * * * Manufactured for Solvecillin, Inc. Division of VCA Laboratories Newark, New Jersey," "Gelucaps Multovals Multi-Vitamins * * * Vitamin Corporation of America Division of VCA Laboratories Newark, New Jersey," "Gelucaps Amberons Vitamin B Complex * * * Vitamin Corporation of America Distributors Newark, New Jersey," and "Ampuls * * * Posterior Pituitary (Obstetrical) * * * VCA Laboratories Newark, New Jersey."

NATURE OF CHARGE: *Penicillin ointment.* Misbranding, Section 502 (1), the article was represented as a drug composed in part of crystalline penicillin potassium salt, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law; and, Section 502 (a), the label statement "Contains: 1000 Units Per Gram of Penicillin Crystalline Potassium Salt" was false and misleading since each gram of the article contained less than 1,000 units of penicillin crystalline potassium salt. Further misbranding, Section 502 (a), the label statement "Expiration Date: February 1951" was misleading in that it represented and suggested that the article could be relied upon to retain its potency until February 1951, whereas the article could not be relied upon to retain its potency until February 1951 since it could not be relied upon to retain its potency for more than one year after the month in which it was manufactured.

Penicillin-G sodium crystalline. Misbranding, Section 502 (1), the article was represented as a drug composed wholly of crystalline penicillin-G sodium, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or a release had been issued pursuant to the law. It was further charged that the defendant, in violation of Section 301 (i), caused to be falsely represented and, without proper authority, to be used on the label of the *Penicillin-G sodium crystalline* certain marks and identification devices authorized and required by the regulations, in that the defendant labeled one shipment of the drug "200,000 Units * * * Lot No. 3467 C Exp. Date Dec. 1950" and labeled the other shipment "100,000 Units * * * Lot No. 3127 C Exp. Date Nov. 1950," which were marks and identifications authorized and required by the regulations to appear in the labeling of crystalline penicillin-G sodium which was from a batch which had been certified pursuant to the regulations, whereas the product so labeled and marked by the defendant was from an uncertified batch.

Multovals Multi-Vitamins Gelucaps. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each gelucap of the article purported and was represented to contain 3 milligrams of vitamin B₁, whereas each gelucap contained less than 3 milligrams of vitamin B₁. Misbranding, Section 502 (a), the label statement "Each gelucap contains * * * Vitamin B₁ . . . 3 mg." was false and misleading.

Amberons Vitamin B Complex Gelucaps. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each gelucap of the article purported and was represented to contain 666 U. S. P. units of vitamin B₁ equivalent to 2 milligrams of vitamin B₁, whereas each gelucap contained less than that amount of vitamin B₁. Misbranding, Section 502 (a), the label statement "Each Gelucap Contains: Vitamin B₁ . . . 666 U. S. P. Units (2 MG.)" was false and misleading.

Posterior pituitary ampuls. Adulteration, Section 501 (b), the article purported to be "Posterior Pituitary Injection," a drug the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from the official standard since its potency was less than the potency required by that compendium. Misbranding, Section 502 (a), the label statements "5 U. S. P. Units * * * Each ½ cc contains: Posterior Pituitary Solution 5 U. S. P. Units" and "U. S. P. * * * 5 Units" were false and misleading. The statements represented and suggested that each ½ cc. of the article possessed a physiologic activity equivalent to 5 U. S. P.

posterior pituitary units, whereas each $\frac{1}{2}$ cc. of the article possessed a physiologic activity equivalent to less than 5 U. S. P. posterior pituitary units.

DISPOSITION: June 13, 1949. A plea of guilty having been entered, the court imposed a fine of \$3,300.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

2936. Misbranding of benadryl capsules, sulfathiazole lozenges, and dexedrine sulfate tablets. U. S. v. Curtis R. Watkins (Krest Drug Store). Plea of *nolo contendere*. Defendant placed on probation for 1 year. (F. D. C. No. 26715. Sample Nos. 27035-K, 27047-K, 27048-K.)

INFORMATION FILED: July 28, 1949, Western District of Arkansas, against Curtis R. Watkins, trading as the Krest Drug Store, Fort Smith, Ark.

INTERSTATE SHIPMENT: On or about March 3 and July 28, 1948, from Kansas City, Mo., and Philadelphia, Pa., of quantities of *benadryl capsules* and *dexedrine sulfate tablets*. The *sulfathiazole lozenges* were manufactured on or about June 3, 1946, at Indianapolis, Ind., and thereafter were shipped in interstate commerce into the State of Arkansas.

LABEL, WHEN SHIPPED: "Kapseals Benadryl * * * 50 Mg. [or "Lozenges Sulfathiazole * * * 5 grs. (0.325 Gm.)" or "5 mg. Each Dexedrine Sulfate Tablets"] Caution: To be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about August 31, September 27, and October 4, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be removed from the bottles in which they had been shipped, to be repacked into boxes, and to be sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded. The repackaged drugs were labeled "Krest Drug Store * * * Fort Smith, Ark. * * * Benadryl 50 mg.," "Sulfathiazal Tablets Take as Directed," and "Dexedrine Tab."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the *sulfathiazole lozenges* and *dexedrine sulfate tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear adequate directions for use since the directions in the labeling of the repackaged *sulfathiazole lozenges* "Take as Directed" were not adequate directions for use and since the other repackaged drugs bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfathiazole lozenges* bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: September 30, 1949. A plea of *nolo contendere* having been entered, the court placed the defendant on probation for 1 year.

*See also Nos. 2931-2934.

2937. Misbranding of Nue-Ovo. U. S. v. 15 Bottles * * *. (F. D. C. No. 25927. Sample No. 37740-K.)

LIBEL FILED: November 17, 1948, Eastern District of Washington.

ALLEGED SHIPMENT: On or about October 21, 1948, by Research Laboratories, Inc., from Portland, Oreg.

PRODUCT: 15 1-pint bottles of *Nue-Ovo* at Spokane, Wash.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to reveal the diseases or conditions of the body for which the article when used as directed would be effective.

DISPOSITION: January 5, 1949. Default decree of condemnation and destruction.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2938. Adulteration of Geo-Mineral. U. S. v. 8 Cases * * * (and 7 other seizure actions). (F. D. C. Nos. 27090, 27100 to 27102, incl., 27114 to 27116, incl., 27376. Sample Nos. 29993-K, 41147-K, 41229-K to 41233-K, incl., 41288-K.)

LIBELS FILED: Between May 4 and 23, 1949, Western District of Washington and District of Utah.

ALLEGED SHIPMENT: Between January 12 and April 8, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

PRODUCT: 1,511 bottles and 8 cases, each case containing 36 bottles, of *Geo-Mineral* at Tacoma, Seattle, Bellingham, and Bremerton, Wash., and Salt Lake City, Utah.

LABEL, IN PART: (Bottle) "Geo-Mineral 3 Fluid Ounces Net * * * Sole Distributor Geo-Mineral Company St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

DISPOSITION: August 10, October 21, and November 2, 1949. Default decrees of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2939. Adulteration and misbranding of Indoform and Pluri-B, and alleged adulteration and misbranding of vitamin D. U. S. v. Pasadena Research Laboratories, Inc., and Russell R. Bavouset. Pleas of not guilty. Tried to the court. Defendants found guilty on five counts and not guilty on two counts. Corporation fined \$3,000; individual defendant placed on probation for five years. Judgment of district court affirmed on appeal to circuit court of appeals. (F. D. C. No. 21441. Sample Nos. 27131-H, 29953-H, 30694-H, 58019-H.)

INFORMATION FILED: March 18, 1947, Southern District of California, against Pasadena Research Laboratories, Inc., Pasadena, Calif., and Russell R. Bavouset, secretary-treasurer.

*See also No. 2935.

ALLEGED SHIPMENT: On or about July 16, September 17, November 19, 1945, and June 18, 1946, from the State of California into the States of Wyoming, Nevada, Washington, and Arizona.

LABEL, IN PART: "Indoform Each cc. Contains: * * * Posterior Pituitary 3 Int'l. Units * * * Thyroid Substance 1 gr."; "Pluri-B * * * Each cc. Contains: Thiamine Hydrochloride . . . 50 Mgms." and "Pluri-B * * * For intramuscular or Intravenous Use"; and "Sterile Injectable Vitamin D (In Oil) * * * 500,000 U. S. P. Units Per cc."

NATURE OF CHARGE: Indoform. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 3 International Units of posterior pituitary and 1 grain of thyroid substance per cubic centimeter, since each cubic centimeter of the article contained less than 3 International Units of posterior pituitary and no thyroid substance. Misbranding, Section 502 (a), the label statement "Each cc. Contains: * * * Posterior Pituitary 3 Int'l. Units * * * Thyroid Substance 1 gr." was false and misleading.

Pluri-B, one lot. Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 50 milligrams of thiamine hydrochloride per cubic centimeter, since each cubic centimeter contained less than that amount of thiamine hydrochloride. Misbranding, Section 502 (a), the label statement "Each cc. Contains: * * * Thiamine Hydrochloride . . . 50 Mgms." was false and misleading.

Pluri-B, remaining lot. Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, in that it purported and was represented to be suitable and appropriate for intramuscular and intravenous administration, a use which requires a product free from undissolved material, whereas the article contained undissolved material.

Vitamin D. Alleged adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, 500,000 U. S. P. units of vitamin D per cubic centimeter, since each cubic centimeter contained less than that amount of vitamin D. Alleged misbranding, Section 502 (a), the label statement "Vitamin D * * * 500,000 U. S. P. Units per cc." was false and misleading.

DISPOSITION: July 7, 1947. Pleas of not guilty having been entered on behalf of the defendants, the case was tried before the court and the defendants were found guilty on all counts, with the exception of counts 5 and 6 involving adulteration and misbranding of vitamin D. The corporation was fined \$3,000; sentence was suspended as to the individual defendant, and he was placed on probation for a period of 5 years. The order provided that during the probationary period, the defendant was to donate \$5 or more each month to an approved charity of his own choice and to obey all laws, Federal, State, and local. An appeal was taken to the United States Circuit Court of Appeals for the Ninth Circuit, and on July 16, 1948, that court affirmed the decision of the district court and handed down the following opinion:

GARRECHT, Circuit Judge: "The appellants were found guilty on five counts of an information charging violations of the Federal Food, Drug, and Cosmetic Act, 21 USCA § 301 et seq., hereinafter referred to as the Act, in that they 'did . . . unlawfully cause to be introduced . . . into interstate commerce' adulterated and misbranded drugs. The corporate appellant was fined \$3,000, and the appellant Bavouset was placed on five years' probation, imposition of sentence upon him having been suspended.

"The trial was without a jury, a jury trial and special findings of fact having been specifically waived in writing.

1. THE FACTS

(A) "INDOFORM"

"It was stipulated as to Counts I and II that a number of vials of 'Indoform' were shipped by the appellants on or about September 17, 1945, from Pasadena, California, to Dr. Joseph C. Bunten, Cheyenne, Wyoming. One vial was picked up as a sample by Ralph M. Davidson, a Federal Food and Drug Inspector, on or about January 24, 1946, from Dr. Bunten, and was sealed and mailed to the Food and Drug Administration at Washington, D. C., hereinafter referred to as the Administration.

"The vials carried labels announcing that each cubic centimeter of the drug contained three International Units of posterior pituitary and one grain of 'thyroid substance.'

"On February 18, 1946, Arnold E. Mason, at that time employed by the Administration as pharmacologist and analyst, examined the contents of the sample vial. He testified that he 'found practically no posterior pituitary in that product, an almost immeasurable quantity.' After conducting the test, Mason replaced the bottle into a locked refrigerator until the next day, when he wrapped it and put a seal on it. The vial was sent to San Francisco, according to his testimony.

"Mason was asked hypothetical questions, objected to by the appellant, as to whether the drug had contained three international units on the date of shipment, September 17, 1945. The questions assumed that the product had not been exposed to the 'destructive temperature' of 212 degrees, had been handled in 'a normal and careful manner,' and had been tested as Mason had already stated on the stand. Mason answered that it was his opinion that on the date in question 'there was a quantity of posterior pituitary which was not measurable by the standard methods of measuring it, or there was none.'

"On March 27, 1946, Andrew G. Buell, a chemist for the Administration, stationed at San Francisco, broke Mason's seal on the paper wrapper around the vial and examined the product for 'thyroid content.' He testified that 'There was no thyroid present whatsoever.' After he made his examination, he 'immediately' put his seal on the bottle. The seal was dated March 28, the day after he examined the contents.

(B) THE DEFICIENT PLURI-B

"As stipulated, a number of vials that form the basis of Counts III and IV were shipped by the appellants to Dr. Clement Swaim, Reno, Nevada, on July 16, 1945. Inspector Frank A. Griebing, of the Administration, picked up two of these vials, which contained Pluri-B, from Dr. Swaim, on August 30, 1945.

"The inspector sealed the vials and contents with official seals, and forwarded them by mail to the Vitamin Division of the Administration at Washington.

"Hubert H. Capps, a chemist of the Administration, examined one of the vials on September 24, 1945. Although the label on the vial sets forth that this 'Sterile Solution of Pluri-B' contains 50 milligrams of Thiamine Hydrochloride, per cubic centimeter, Capps testified that he found it contained approximately only 33 milligrams per cc.

"The Government chemist also stated that at the time he received the vial, it had the same cap that it had at the time he was testifying, 'or one very similar to it,' adding that 'since this does not appear to be broken, I think that it did have that identical cap.' He also said, however, that he did not make any examination of the cap to determine whether or not it was punctured in any way, 'other than just looking at it.'

"During the direct examination of Capps, he was asked the following hypothetical question, which the appellants contend was improper because it assumed facts none of which 'are supported by any evidence whatever':

Now, assuming that the product received ordinary and reasonable care, and was not exposed to excessive heats, such as heats any more than would be normal from shipping

and the weather, and basing upon what you found on September 24, 1945, the amount of the B-1 or thiamine chloride that you found, have you an opinion as to what percentage or what amount that product, substance, or solution had on or about July 16, 1945, the date it was originally shipped?

"Capps replied that he believed that it did not contain more than 33 milligrams of thiamine hydrochloride per cubic centimeter.

(C) THE CONTAMINATED PLURI-B

"According to the stipulation, a number of vials with labels, which form the subject-matter of Count VII, were shipped by the appellants on June 18, 1946, to Dr. P. M. Ryerson, Phoenix, Arizona. The vials contained 'Pluri-B,' and, according to the labels, the contents were 'for intramuscular or intravenous use.'

"On or about July 12, 1946, Maurice P. Kerr, an inspector for the Administration, collected a sample consisting of six vials and their contents, each at random from different boxes of the shipment in Dr. Ryerson's possession. The inspector marked the labels, sealed the vials with official seals, and forwarded them by express to the Administration at Washington.

"Dr. Frank H. Wiley, chief of the chemical section of the medical division of the Administration, holding a doctor's degree in biochemistry, testified that he received the sample on July 23, 1946. He put the vials up to a light and found 'with the naked eye' that all six of them 'were very badly contaminated with undissolved material.'

"Dr. Wiley was asked the following hypothetical question, which the appellants assert was 'bad and improper because it did not include a sufficient factual basis to support an opinion':

Q. . . . Dr. Wiley, taking the two vials, . . . which I understand you examined about six weeks after the shipment in question here, from your knowledge of sterile solutions and from your observation of sterile solutions, your experience, are you able to express an opinion to this court as to whether or not the contents of those two vials, . . . did contain the undissolved particles you noticed there then as of the date they were shipped, namely, on or about June 18, 1946? Your answer is yes or no.
A. Yes.

Q. . . . Will you please relate your opinion?

"The appellants object that in the foregoing questions 'no mention whatever was made of the conditions to which the drug had been subjected after shipment by appellants.'

"Dr. Wiley's answer to the question was as follows:

A. From experience with these materials and from general information of so-called supersaturated solutions, of which this is an example, I would say that this undissolved material was undoubtedly present on June 18th when the material was shipped. There is only one external factor of which I know that would hasten or increase the crystallization of this material, and that would be refrigeration. I doubt very much if the mail bag in which this material was transmitted to Washington was in a refrigerator car.

"The appellants comment that 'even if the question was proper Wiley's opinion given in response thereto is not entitled to any weight whatever.'

"Other evidence relating to the drugs in question will be referred to in appropriate places in the discussion that follows.

2. THE CANON OF CONSTRUCTION

"The Act is remedial, and should be liberally construed so as to carry out its beneficent purposes."

"In *United States v. Dotterweich*, 320 U. S. 277, 280, the Court said of this statute:

The purposes of this legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words. [Cases cited.]

"As we will point out hereafter, we are here being asked to accept defensive refinements that we believe are as gossamer-like as the traditional 'shadow of a shade' of the ancient legal commentators. We have recently had occasion to construe this same statute and have endeavored to do so in the liberal spirit commanded by the Supreme Court. *Research Laboratories, Inc. v. United States* [CCA 9], 167 F. 2d 410, 421. In the instant case, we do not feel disposed to depart from that same generous norm of interpretation, which we believe accords with public policy and with the spirit of the law itself.

3. THE GOVERNMENT'S BURDEN AND THE APPELLATE FUNCTION

"The appellants seem to be laboring under a fundamental misconception regarding (1) the degree of proof required from the appellee and (2) the duty of this court in the evaluation of the evidence. Because these misapprehensions are basic, we will endeavor to clear them away at the outset.

(A) "REASONABLE" VERSUS "POSSIBLE" DOUBT

"While the appellants professedly recognize the rule that the Government must prove its case beyond a *reasonable* doubt, their briefs are replete with expressions which seem to indicate that in reality the standard actually insisted upon is that the appellee's evidence should remove all *possible* doubt.

"For example, we are twice told that 'The Government failed to eliminate the possibility of the drugs having lost their strength . . . or having undissolved material formed or introduced in it . . . between the dates of shipment and the dates of the Government tests.' Again, after enumerating many dire vicissitudes through which the drugs in question might have passed—such as improper handling, the use of hypodermic needles containing certain chemicals, and the like—the appellants suggest: 'Any one of the above things *may* have occurred even while in the inspector's hands, or during shipment by the inspector to Washington, D. C.' [Italics supplied.]

"Elsewhere we find a variation of the same theme: 'Furthermore, there was no evidence *precluding the possibility* that the drugs became adulterated and misbranded *at some time* after they had been shipped by appellants from Pasadena, California.' [Italics supplied.] Finally, in the reply brief we find the statement that 'still the Government cannot prevail because the Government introduced no evidence to show that any of the above things did not happen.'

"While in other portions of their briefs the appellants do complain that the Government failed to adduce certain affirmative evidence, their insistence also upon the lack of *negative* evidence indicates that they are holding the appellee to too strict a standard of proof; namely, the proof of several negatives.

"In *Henderson v. United States* [CCA 9], 143 F. 2d 681, 682, we said:

The proof in a criminal case need not exclude all doubt. If that were the rule, crime would be punished only by the criminal's own conscience, and organized society would be without defense against the conscienceless criminal and against the weak, the cowardly and the lazy who would seek to live on their wits. The proof need go no further than reach that degree of probability where the general experience of men suggests that it has passed the mark of reasonable doubt.

See also *Rose v. United States* [CCA 9], 149 F. 2d 755, 759.

(B) THE WEIGHT OF THE EVIDENCE

"In the second place, the appellants' briefs contain frequent references to the *weight* of the evidence. For example, complaint is made that 'The finding of guilty by the Trial Court is, therefore, contrary to the weight of the evidence'; that certain allegedly contradictory testimony by Mason 'does nothing more, it is submitted, than detract from the weight of any of Mason's testimony'; that 'the findings of guilty by the Lower Court are contrary to the weight of the evidence'; that 'Mason was biased and gave contradictory testimony'; and that 'the best evidence is the testimony of Bavouset,' etc.

"While as to this question, too, the appellants elsewhere in their briefs assert a *total* lack of evidence to support the Government's case, their constant insistence on the irrelevant question of the *weight* of the evidence indicates that a certain confusion on this subject exists in their minds.

"To clarify the matter for once and for all, we wish to restate plainly that this court is not concerned with the *weight* of the testimony adduced below. 'Questions of credibility were for the trial court.' *Newman v. United States* [CCA 9], 156 F. 2d 8, 10, certiorari denied *sub. nom.* *Cain v. United States*, 329 U. S. 760.

(C) THE PRESUMPTION SUPPORTING THE TRIAL COURT'S JUDGMENT

"As a corollary to the above proposition, there need be only briefly mentioned the equally familiar doctrine relative to the weight that even in a criminal case

should be given to the judgment or the verdict in the trial court. The rule, with its necessary implications, was thus succinctly stated by this court in *Henderson v. United States*, supra, 143 F. 2d at page 682:

It is a familiar principle, which it is our duty to apply, that an appellate court will indulge all reasonable presumptions in support of the rulings of a trial court and therefore that it will draw all inferences permissible from the record, and in determining whether evidence is sufficient to sustain a conviction, will consider the evidence most favorably to the prosecution. [Cases cited.]

4. THE IDENTITY OF THE SAMPLES

"The appellee 'has no quarrel' with the proposition that the burden is on the Government to establish that in reasonable probability the testimony of its witnesses regarding the condition of the drugs as of the date of analysis substantially reflects their condition on the date of shipment.

"The controversy between the parties arises in the application of this familiar principle to the facts at bar. The appellants seem to insist on what would amount to a mathematical demonstration that there was no tampering with the vials anywhere along the line, from the date the products left the custody of the appellants to the date when the drugs were examined and analyzed in Washington or San Francisco. The appellee, on the other hand, asserts that it has undertaken 'to establish the identity of the samples *as of the time of shipment*, by circumstantial evidence relating to their interstate shipment, the identity of the consignees and the condition of the drugs when received by the Government chemists, together with the reasonable inferences flowing from such evidence.'

"We will now examine these divergent assertions in greater detail.

(A) "THE CHAIN OF POSSESSION"

"The appellants contend that the opinions of the Government's witnesses, based on tests made after the drugs had been shipped to Washington are 'absolutely worthless because the expert witnesses had no knowledge that the alleged adulteration or misbranding did not occur enroute to the doctor's office, or in the doctor's office, or in the hands of the Government inspectors who picked up the drugs, or enroute to Washington, D. C., when shipped there by the Government inspectors.'

"Carried to its logical conclusion, this 'chain of possession' theory would require the Government to prove affirmatively that *each* one of the many mail clerks, Administration clerks and experts, doctors, nurses, express company employees, 'and others,' handled and cared for the goods so that changes could not occur while the drugs were in their custody. It must also be shown that the products 'were not tampered with,' say the appellants.

"Such a rigorous exaction regarding proof is supported neither by reason nor by authority. If the Government was obliged to establish the absence of 'tampering' by every one who had any contact whatsoever with the drugs, the Act would be incapable of enforcement.

"In *Lestico v. Kuehner* [Minn.], 283 N. W. 122, 125, the court derided 'the unique theory' that it was incumbent to show the 'chain of possession' of a punctured tire casing offered in evidence after it had been repaired, 'during the whole period from accident to trial.' The court said:

The tire had been removed and repaired in Minneapolis. The thought of objections and sustaining rulings was that no sufficient foundation could be laid except by testimony not only as to genuineness, but also the absence of tampering, from every person through whose hands the casing had passed in the meantime. There is no such rule and never has been. [Italics supplied.]

"In quoting authorities to support their position, the appellants significantly omit two pertinent passages from their excerpts. From the opinion in *United States v. S. B. Penick & Co.* [CCA 2], 136 F. 2d 413, 415, they delete the following sentences:

But there is no hard and fast rule that the prosecution must exclude all possibility that the article may have been tampered with. [Citing *Lestico v. Kuehner*, supra] * * * Here the samples were taken in the ordinary course of business for the very purpose of being retained as samples; they were put in the usual place where samples were kept to remove them from accident or meddling and there they remained, so far as appear[s], undisturbed. We think this showing was sufficient to justify admission in evidence of the bottles and their contents and that it was for the jury to decide how likely it was that some other substance had been substituted for what was originally put in the bottles. [Cases cited.]

"Similarly, the appellants omit the following sentences from the very middle of their quotation from 32 C. J. S. § 607, at pages 457-458:

However, it is not necessary that the article be identically the same as at the time in controversy. It is unnecessary to show an absence of tampering on the part of every person through whose hands the article has passed; as long as the article can be identified it is immaterial in how many or in whose hands it has been. A direct statement that the article was in the same condition at the time of an occurrence as at a subsequent time is not required if it sufficiently appears that it must have been in substantially the same condition.

(B) THE PRESUMPTION OF REGULARITY

"Buttressing the natural and reasonable inferences that may be drawn from the stipulations and the testimony regarding the marking, sealing and opening of the vials in question, there are certain well-established presumptions regarding the regularity not only of the acts of public servants but also of the acts of private individuals.

I. OF THE ACTS OF PUBLIC SERVANTS

"In *United States v. Chemical Foundation*, 272 U. S. 1, 14-15, the familiar rule as to the acts of public officers is thus stated:

The presumption of regularity supports the official acts of public officers and, *in the absence of clear evidence to the contrary*, courts presume that they have properly discharged their official duties. [Cases cited.] [Italics supplied.]¹

"In the instant case, this presumption of official regularity would apply not only to the methods used by the Government chemists and analysts in handling the vials, but also to the care and to the absence of tampering on the part of the postal employees through whose hands the shipments passed. *Boerner v. United States* [DC NY], 30 F. Supp. 635, 637, affirmed, 117 F. 2d 387, certiorari denied, 313 U. S. 587.

II. OF THE ACTS OF PRIVATE INDIVIDUALS

"While the appellants reluctantly concede that there 'may' be a presumption supporting the official acts of public servants, they insist that 'there is no presumption whatever' with respect to 'shippers,' doctors, nurses, 'and others.'

"We do not agree.

"In *United States Bank v. Dandridge*, 25 U. S. 64, 69-70, Mr. Justice Story said:

By the general rules of evidence, presumptions are continually made, in cases of private persons, of acts even of the most solemn nature, when those acts are the natural result or necessary accompaniment of other circumstances. In aid of this salutary principle, the law itself, for the purpose of strengthening the infirmity of evidence, and upholding transactions, intimately connected with the public peace, and the security of private property, indulges its own presumptions. It presumes, that every man, in his private and official character, does his duty, until the contrary is proved [cases cited]; it will presume that all things are rightly done, unless the circumstances of the case overturn this presumption, according to the maxim, *omnia presumuntur rite et solemniter esse acta, donec probetur in contrarium*.

"This early decision and the doctrine that it enunciates were referred to with approval in *International Shoe Company v. Federal Trade Commission*, 280 U. S. 291, 302, where reference was made to 'the familiar presumption of rightfulness which attaches to human conduct in general.'²

"This presumption that even private individuals do their duty and exercise due care should apply a fortiori to doctors and nurses, whose professional training and traditions teach them to be meticulous in the handling of preparations that are to be administered to their patients.

"Indeed, in the instant case, this presumption is supported by the affirmative testimony of one of the appellants' own witnesses. Dr. Roland N. Icke, director of research at the appellants' laboratories, said while under cross-examination:

Q. . . . It has been your practice and observation of most doctors that they try to keep their bottles in proper places, has it not, Doctor?

¹ See also *Bowles v. Gluck Bros. Lumber Co.* [CCA 9], 146 F. 2d 566, 571, certiorari denied, 325 U. S. 877; *Dunn v. Ickes* [CA DC], 115 F. 2d 36, 37, n. 8, certiorari denied, 311 U. S. 698; *Middlesboro Liquor & Wine Co., Inc. v. Berkshire* [CA DC], 133 F. 2d 39, 42.

² See also *Powell Bros. Truck Lines v. Piatt* [CCA 10], 92 F. 2d, 879, 880; 31 C. J. S. § 150 e, page 840.

A. I believe most of them do; yes.

Q. And it is rare that you find a doctor but what he adheres to the cautions that he has been instructed; isn't that correct?

A. Yes.

"The appellants have not pointed out, nor have we been able to find, a single scintilla of evidence in the record to indicate that any of the vials were mishandled by a single postal clerk, expressman, doctor, nurse, Government analyst, Administration mail clerk, or *any one else* who had any connection with the sealing, labeling, consignment, transmission, unwrapping, unsealing, or testing of the products in question.

"The only suggestions of mishandling are in the form of *dire possibilities* conjured up by resourceful counsel. But possibilities are not proof.

5. THE SO-CALLED "DISCLAIMER"

(A) SHOULD "THYROID SUBSTANCE" CONTAIN IODINE?

"It will be recalled that, although the label on the vials of 'Sterile Indoform' announced that each cubic centimeter of the contents carried one grain of 'thyroid substance,' Buell, the Administration's chemist, found 'no thyroid present whatsoever.'

"The appellants seek to avoid the impact of Buell's testimony by pointing out that, according to his own statement, the only thing that he examined the product for 'was for the therapeutically active ingredients of thyroid, which were the organically combined iodine products.' In other words, he examined 'only for iodine.'

"Buell also testified, however, that the label statement regarding 'thyroid substance' means that each cubic centimeter contains 'one grain of the active constituent of the thyroid,' 'as organically combined iodine.' 'The activity of thyroid,' he explained, 'depends on the organically combined iodine present in the thyroid.'

"The appellants freely admit that there never was any iodine in 'Indoform.' They point to Buell's own testimony, however, that there would be present in a thyroid gland 'other things' besides iodine. From this the appellants argue that the words 'thyroid substance' do not necessarily imply that the preparation contains iodine.

(B) AT BEST THE LABEL TELLS ONLY A HALF-TRUTH

"The appellants seek to bolster up this argument by pointing out that the label itself contains the notation:

This preparation does not contain any known therapeutically useful constituent.

Since iodine is a therapeutically useful ingredient, they say, the label itself indicates that iodine is not present.

"There are two answers to this argument. In the first place, this so-called disclaimer itself is untruthful. The appellant Bavouset himself admitted on the stand that posterior pituitary, which, as we have seen, is one of the ingredients of 'Indoform,' *does* have therapeutic value. He also testified that he 'didn't manufacture' whole ovarian, another constituent, to be a meaningless product. The appellants seek—without avail, we think—to weaken the effect of this testimony by Bavouset's later lame and somewhat cryptic explanation that 'In this particular solution, this form would not be measurable.' In any event, we cannot say that the court erred if it believed from the evidence—as we do—that posterior pituitary and whole ovarian *do* have some therapeutic value.

"Assuming, however, for the sake of the argument, that the 'disclaimer' does tell the truth, it cannot cure the vice of the half-truth or equivocation in the use of the expression 'thyroid substance' in a preparation that contains no iodine. Section 321 (n) of 21 USCA provides that *omissions* as well as representations shall be taken into account in determining whether the labeling is misleading.

"In *Research Laboratories v. United States*, supra, 167 F. 2d at page 418, we held that 'the scientific half-truths in the labeling alone make out a case of actionable misbranding.'

"Specific reference to self-contradictory labels is found in *H. N. Heusner & Son v. Federal Trade Commission* [CCA 3], 106 F. 2d 596, 597:

Accordingly, the petitioner, a Pennsylvania manufacturer of cigars which contain only Pennsylvania tobacco, but are branded "Havana Smokers," has been ordered to cease and desist from using the word "Havana" to designate its product. We are asked to modify this order so as to permit the retention of the word "Havana" with an appropriate "qualification," i. e., the legend: "Notice. These Cigars are made in the United States and only of United States tobacco."

The difficulty of petitioner's position lies in the fact that the implication of the word "Havana" is totally false. The purchaser can be guided by either label or legend, but not by both. [Emphasis supplied.]³

"So here, the purchaser of 'Indoform' could be guided by either the labeling 'thyroid substance,' which implies the presence of a therapeutic ingredient, or by the 'disclaimer' of the presence of *any* such ingredient. Obviously, the implication of presence and the negation of presence cannot both be true.

"In the language of the day, this 'Indoform' label strikes us as a bit of scientific 'double-talk.'

"The Supreme Court has repeatedly denounced equivocation and evasion by those who come within the reach of a statute that enunciates Governmental policy. Whether the subterfuge is accomplished by suppression or contradiction, the vice is the same.

"Referring to the Food and Drugs Act of 1906, the Supreme Court, in *United States v. 95 Barrels of Vinegar*, 265 U. S. 438, 442-443, used the following language:

The statute is plain and direct. Its comprehensive terms condemn every statement, design and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act.⁴

"So here, it would have been 'not difficult to choose statements' that would not deceive. The simple legend, 'This preparation does not contain iodine,' would have been sufficient.

6. THE HYPOTHETICAL QUESTIONS

"The appellants object to certain hypothetical questions that were propounded to three of the Government's experts. These questions have already been quoted by us, either verbatim or in substance, in our outline of the facts.

(A) THE QUESTIONS PRESENTED SUFFICIENT FACTS IN EVIDENCE

"The appellants' first two attacks upon these hypothetical questions may be considered together. They are (1) that the question addressed to Dr. Wiley did not contain sufficient facts to afford ground for a reasonable conclusion or opinion, and (2) that the question asked of Mason and Capps assumed facts not in evidence.

"From the facts already stated, supplemented by the reasonable inferences flowing therefrom and by the presumptions of regularity that, as we have seen, are firmly recognized in the law, it is clear that the hypothetical questions referred to were not objectionable. We need not labor the factual aspects further.

"Moreover, it should be remembered that the rule requiring a factual basis for a hypothetical question is not applied with iron rigidity.

"In *Permanente Metals Corporation v. Pista* [CCA 9], 154 F. 2d 568, 569, we said:

Moreover, it has been held in California, as elsewhere, that where a witness answers a hypothetical question not founded on all the facts of the case, the defect goes not to the competency of the evidence but merely affects its weight.

"And in the earlier case of *Travelers Ins. Co. v. Drake* [CCA 9], 89 F. 2d 47, 50, this court used the following language regarding the factual latitude that might be allowed:

The question may be framed upon any theory of the interrogator, which can reasonably be deduced from the evidence; any assumptions may be indulged on any fact within

³ See also *El Moro Cigar Co. v. Federal Commission* [CCA 4], 107 F. 2d 429, 431; *Progress Tailoring Co. v. Federal Trade Commission* [CCA 7], 153 F. 2d 103, 105.

⁴ See also *Donaldson v. Read Magazine*, 333 U. S. 178, 188-189.

the evidence, upon which opinion is desired by the interrogator; and facts not deemed material may be omitted. [Many cases cited.] The truth of facts assumed by the hypothetical question as within the probable range of the evidence, as a basis to support the hypothetical question, is a question of fact for the determination of the jury to find with the other submitted facts upon a fair submission of the issue, and it must determine whether the basis upon which the hypothetical question rests has been established. [Authorities cited.] When the question assumes a state of facts which the evidence directly, fairly, and reasonably tends to establish, and does not transcend the range of the evidence, it is not objectionable. [Cases cited.]⁵

(B) THE QUESTIONS DID NOT DEAL WITH "ULTIMATE ISSUES"

"The appellants further urge that *all* the hypothetical questions violated the 'rule of law' 'excluding the opinions of experts as to the ultimate issues of fact to be determined.'

"This objection is not well grounded. A glance at the questions discloses that in none of them is there any reference to 'misbranding' or 'adulterating,' which are the ultimate issues in this case. Dr. Wiley was asked whether he thought that the two vials of Pluri-B contained the undissolved particles on June 18, 1946, the date on which they were shipped. The question addressed to Mason was whether the 'Indoform' contained three international units of posterior pituitary on September 17, 1945. The hypothetical question directed to Capps related to the amount of thiamine hydrochloride in the Pluri-B on the date when it was shipped by the appellants, July 16, 1945.

"All these questions dealt with *supporting* or *evidentiary* facts, and not ultimate issues. It is true that the facts inquired about were *related* to the ultimate issues; else the hypothetical questions would have been irrelevant, and the appellants would now be clamoring that the questions were improper on the ground of immateriality.

"In *Travelers Ins. Co. v. Drake* [CCA 9], *supra*, 89 F. 2d at page 49, this court said:

While the jury is the sole judge of the facts as to the issue of death and cause of death, that does not, however, make objectionable the opinion of a medical expert in aid to the jury to find the ultimate fact. [Many cases cited.]⁶

"Furthermore, this court has repeatedly held that the fairness of a hypothetical question is largely a matter that lies within the discretion of the trial judge."

(C) THE TRIAL JUDGE IS PRESUMED TO CONSIDER ONLY COMPETENT EVIDENCE

"Even if certain deficiencies had crept into any of the hypothetical questions—which we most certainly do not concede—in this and in other circuits it is presumed that the trial judge considered only competent evidence in arriving at his judgment.

"In *Hoffman v. United States* [CCA 9], 87 F. 2d 410, 411, we said:

This case was tried by the judge and presumably he would consider only material and competent testimony.⁸

7. THE APPELLANTS' ADMITTED LACK OF TESTING EQUIPMENT

"Capps said on the stand that he tested the contents of one of the vials in evidence for thiamine hydrochloride, and that he used a 'Thiachrome procedure.' This test was made on September 24, 1945.

"Immediately following Capps as a witness was the appellant Bavouset. The latter was cross-examined at some length regarding a hearing of the Administration conducted by a Mr. Rowe on November 7, 1945. The record shows the following:

Q. And did you not likewise state to Mr. Rowe at the hearing on or about November 7, 1945, with regard to the Pluri-B and the thiamine deficiency, that you did not have

⁵ See also *Moyer v. Aetna Life Ins. Co.* [CCA 3], 126 F. 2d 141, 144.

⁶ See also *Francis v. Southern Pacific Company* [CCA 10], 162 F. 2d 813, 817, affirmed, 333 U. S. 445; *United States v. 7 Jugs, etc., of Dr. Salsbury's Rakos* [DC Minn.], 53 F. Supp. 746, 760.

⁷ *Travelers Ins. Co. v. Drake* [CCA 9], *supra*, 89 F. 2d at page 50; *United States v. Aspinwall* [CCA 9], 96 F. 2d, 867, 869; *Permanente Metals Corporation v. Pista* [CCA 9], *supra*, 154 F. 2d at pages 569-570. Cf. *Moyer v. Aetna Life Ins. Co.* [CCA 3], 126 F. 2d at page 144.

⁸ See also *United States v. David* [CCA 7], 107 F. 2d 519, 522; *Murray v. United States* [CCA 8], 117 F. 2d 40, 45; *Gates v. United States* [CCA 10], 122 F. 2d 571, 578, certiorari denied, 314 U. S. 698; *Daniel v. United States* [CCA 8], 127 F. 2d 1, certiorari denied, 317 U. S. 641.

the equipment to make the thiachrome determination for thiamine and that you would have to, therefore, revise your manufacture and procedure?

A. We did not have the equipment. Now, about the revision of manufacturing procedure, that goes on almost every day.

"The appellee refers to this lack as constituting 'poor manufacturing controls.' In resisting this charge, the appellants, in their reply brief, run into another admission:

When the Government uses the term "poor manufacturing controls" it undoubtedly refers to the *fact* that appellants did not always test their products at the conclusion of the manufacture. [Emphasis supplied.]

"All this, we think, further supports the trial court's judgment that the appellants' products in question were so deficient or contaminated as to result in a violation of the Act.

8. CONCLUSION

"While in the foregoing discussion we have copiously referred to the transcript, we have not attempted to give a complete summary of the evidence. To have done so would have unduly lengthened this opinion.

"Our careful study of the entire record, however, has convinced us that there was no error in the judgment below, and it is accordingly affirmed."

2940. Adulteration of Pamestrogen Suspension. U. S. v. 90 Vials * * *. (F. D. C. No. 27450. Sample No. 31837-K.)

LIBEL FILED: July 1, 1949, Southern District of California.

ALLEGED SHIPMENT: On or about January 3, 1949, by Hema Drug Co., Inc., from Maspeth, N. Y.

PRODUCT: 90 10-cc. vials of *Pamestrogen Suspension* at Los Angeles, Calif. The article was unlabeled when shipped but was invoiced as "a suspension consisting of * * * Estradiol (0.225 mgm. per cc.)." Analysis showed that it contained 0.045 mgm. of alpha estradiol per cubic centimeter.

LABEL, IN PART: (Label applied after shipment) "Pamestrogen Suspension An Aqueous suspension of Estrogenic Hormones Each cc. contains 0.225 milligrams of Estradiol."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 0.225 milligrams of alpha estradiol per cubic centimeter.

DISPOSITION: August 18, 1949. Default decree of condemnation and destruction.

2941. Adulteration of Vibarso. U. S. v. 80 Vials * * *. (F. D. C. No. 27475 Sample No. 43494-K.)

LIBEL FILED: On or about August 4, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: On or about June 3, 1949, by the Vitamix Corp., from Philadelphia, Pa.

PRODUCT: 80 vials of *Vibarso* at Chicago, Ill.

LABEL, IN PART: "30 cc. Multiple Dose Vial Vibarso Bismuth Dimethyl-arsenate Sterile—Intramuscular."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it was represented to be for intramuscular use and it contained undissolved material, whereas an article which is represented to be for intramuscular use should be substantially free of any undissolved material.

DISPOSITION: October 17, 1949. Default decree of condemnation and destruction.

2942. Adulteration and misbranding of prophylactics. U. S. v. 35 Gross * * *.
(F. D. C. No. 27454. Sample No. 83435-K.)

LABEL FILED: July 7, 1949, Northern District of California.

ALLEGED SHIPMENT: On or about June 4, 1949, by Hughes Products, Inc., from Memphis, Tenn.

PRODUCT: 35 gross of *prophylactics* at San Francisco, Calif. Examination of samples showed that 4.86 percent were defective in that they contained holes.

LABEL, IN PART: "Texide Prophylactic * * * Manufactured by L. E. Shunk Latex Prod., Inc., Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactic" and "Tested * * * For Your Protection" were false and misleading as applied to an article containing holes.

DISPOSITION: August 25, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

2943. Misbranding of Sugretus and dehydrated wild carrot. U. S. v. Albert D. Davis (Universal Health Foods). Motion denied for dismissal of information. Plea of *nolo contendere*. Imposition of sentence suspended and defendant placed on probation for 2 years. (F. D. C. No. 24219. Sample Nos. 39567-H, 24601-K.)

INFORMATION FILED: February 13, 1948, Eastern District of Michigan, against Albert D. Davis, trading as Universal Health Foods, Van Dyke, Mich.

ALLEGED SHIPMENT: On or about May 29 and September 9, 1947, from the State of Michigan into the State of Wisconsin.

LABEL, IN PART: "Tablets Sugretus * * * Contains: Vitamin B₁ (Thiamin Chloride) and Vitamin B₂ (Riboflavin) in a base of powdered Spineless Cactus (*Opuntia Frarlis*) with excipients Manufactured & Distributed By Dailey's Laboratories 3680 University Ave. San Diego, Calif." and "Dehydrated Wild Carrot * * * Universal Health Foods."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in a leaflet headed "Freed From Insulin Diabetics Find New Help" and in a letter dated September 13, 1946, headed "Dr. Julia Bryant McGee Chiropractor," accompanying the *Sugretus*, and in leaflets entitled "Goodbye Insulin New Hope for Diabetics" and "Good News for All Who Are 'Afraid of Starch and Sugar,'" accompanying the *dehydrated wild carrot*, were false and misleading. The statements represented and suggested that the articles would be efficacious in the cure, mitigation, and treatment of diabetes, whereas the articles would not be efficacious for such purposes.

DISPOSITION: On March 22, 1948, a motion to dismiss the information was filed on behalf of the defendant on the grounds that the leaflets and other printed matter did not actually physically accompany the products nor were made a part of the labels of the articles. On October 29, 1948, the motion was denied. Thereafter, a plea of *nolo contendere* was entered, and on September 30, 1949,

*See also Nos. 2931-2933, 2935, 2939, 2942.

the court suspended the imposition of sentence and placed the defendant on probation for a period of 2 years, conditioned that he should not sell, dispense, or give away any *Sugretus* or *dehydrated wild carrot* during the period of probation, either in interstate commerce or intrastate commerce.

2944. Alleged misbranding of Bra'zil Liquid Compound and Bra'zil Powder Compound. U. S. v. Yancy T. Shehane (Bra'zil Medicine Co.) Plea of not guilty. Tried to the jury. Verdict of not guilty. (F. D. C. No. 25588. Sample Nos. 27350-K to 27353-K, incl.)

INDICTMENT RETURNED: February 7, 1949, Western District of Arkansas, against Yancy T. Shehane, trading as the Bra'zil Medicine Co., at Arkadelphia, Ark.

ALLEGED SHIPMENT: On or about February 8 and March 8, 1948, from the State of Arkansas into the States of Illinois and Missouri.

LABEL, IN PART: "Bra'zil Liquid Compound Alcohol * * * 13½ % * * * Active Ingredients: Sodium Salicylate" and "Bra'zil Powder Compound Active Ingredients: Epsom Salts."

NATURE OF CHARGE: Misbranding, Section 502 (a), it was alleged that certain statements in the labeling of the articles, including an accompanying leaflet entitled "You May Be Interested In This Medicine—It really Works," were false and misleading in that they represented and suggested that the articles, which were designed and intended for use as a combination treatment, would be efficacious in the treatment of arthritis, neuritis, sciatica, inflammatory rheumatism, rheumatic fever, sinus trouble, bronchial asthma, ulcerated gassy stomachs, kidney pus, gall bladder irritation, prostate gland trouble, nervousness, general poison conditions of the system, aches, pains, swelling, and soreness; and, further that the articles would not be efficacious in the treatment of the conditions represented.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial on October 4, 1949. At the conclusion of the trial on October 5, 1949, the jury returned a verdict of not guilty.

2945. Misbranding of Thiacin. U. S. v. William Teffer (Thiacin Co.). Plea of nolo contendere. Fine, \$500. (F. D. C. No. 26692. Sample No. 27323-K.)

INFORMATION FILED: May 16, 1949, Eastern District of Missouri, against William Teffer, sales director of the Thiacin Co., a partnership, St. Louis, Mo.

ALLEGED SHIPMENT: On or about August 9, 1948, from the State of Missouri into the State of Illinois.

LABEL, IN PART: "Thiacin The Enteric Coated Relief Tablet * * * Each Tablet contains Sodium Salicylate, Thiamin Hydrochloride (10 mg.) Acetylsalicylic Acid, Enteric Coated with Excipient."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article, which included a number of accompanying circulars entitled "Ask Yourself This Question," was false and misleading. The labeling represented and suggested that the article would be adequate and effective for the treatment and cure of arthritis, rheumatism, neuralgia, neuritis, and muscular lumbago. The article would not be adequate and effective for the treatment and cure of the conditions represented.

Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients; and its label failed to bear the common or usual name of each active ingredient since one of the active ingredients of the article

was aspirin, and the label of the article failed to declare aspirin by its common or usual name.

DISPOSITION: August 16, 1949. A plea of *nolo contendere* having been entered, the court imposed a fine of \$500.

2946. Misbranding of Topacold. U. S. v. 350 Dozen Packages * * * (and 2 other seizure actions). Cases removed and consolidated. Motion to dismiss libels overruled. Default decree of condemnation and destruction. (F. D. C. Nos. 15316, 16137, 16150. Sample Nos. 25535-H, 26608-H, 26610-H, 26611-H, 27813-H to 27816-H, incl.)

LIBELS FILED: On or about February 28 and May 18 and 23, 1945, District of Colorado, Western District of Washington, and District of Utah.

ALLEGED SHIPMENT: On or about December 20 and 22, 1944, and January 5, 8, and 20, 1945, from Los Angeles, Calif., by the Topical Products Corp. and Thornlee, Inc.

PRODUCT: *Topacold*. 350 dozen packages at Denver, Colo.; 1,837 packages at Seattle, Wash.; and 468 cartons, each containing one vial, at Salt Lake City, Utah. Examination showed that the product consisted essentially of a perfumed mixture of water and alcohol; phenols, such as cresols, 1%; gum; and not more than a trace, if any, of cottonseed oil; and that it contained no carotene nor vitamin A.

NATURE OF CHARGE: Misbranding, Section 502 (a), the designation "*Topacold*" and certain statements on the carton and bottle labels, on the display cartons, in accompanying leaflets entitled "*Topacold For the relief of common virus head colds,*" on accompanying circulars entitled "*At Last! A Scientific Treatment for the Relief of the Common Virus Head Cold,*" and on accompanying window posters entitled "*Don't Let a Virus Head Cold Stop You,*" were false and misleading. The designation "*Topacold*" and the statements represented and suggested that the article was effective in the cure and mitigation of a cold and to otherwise affect the course of a cold, and that it was effective to alleviate sneezing, running of the nose, watering of the eyes, and the general discomfort or distressing conditions accompanying colds, whereas the article was not effective for such purposes.

Further misbranding, Section 502 (a), the label statement "*Topacold* * * * Contains: Derivatives of Carotene in cottonseed oil * * * Uncombined cresols 0.05%" was false and misleading since the article contained no carotene nor vitamin A, the only known therapeutically useful derivative of carotene, and not more than a trace, if any, of cottonseed oil; and the article contained much more than 0.05% cresols.

DISPOSITION: Following the seizure of the product, the libel proceedings against each lot were removed to, and consolidated for trial in, the Northern District of California. Thereafter, Thornlee, Inc., claimant, filed a motion for dismissal of the proceedings on the grounds (1) that the Government illegally and in violation of the law filed a multiplicity of suits involving the same cause of action; (2) that the court was without jurisdiction to entertain the libels; (3) that the libels were brought by the Government in bad faith and for the sole purpose of harassing the claimant and without justifiable cause or reason; and (4) that the libels were being maintained by the Government in breach of good faith with the claimant.

On January 14, 1948, after consideration of the briefs, the court overruled the motion to dismiss. On January 27, 1950, a stipulation was entered into

between the parties to permit the claimant to withdraw its claims upon payment of costs, but with the understanding that the claimant did not admit the misbranding of the product and that the entry of a default decree in the case should not be deemed an adjudication of the issues on the merits. In accordance with such stipulation, the court ordered that the claims be withdrawn; and on February 3, 1950, a default decree of condemnation and destruction was entered.

2947. Misbranding of medicated douche powder. U. S. v. 13 Dozen Cans * * *.
(F. D. C. No. 27291. Sample No. 41471-K)

LIBEL FILED: June 2, 1949, Western District of Washington.

ALLEGED SHIPMENT: On or about February 11, and April 23, 1949, by Stanley Drug Products, Inc., from Portland, Oreg.

PRODUCT: 13 Dozen 5-ounce cans of *medicated douche powder* at Seattle, Wash. Analysis showed that the product consisted essentially of boric acid, alum, zinc sulfate, carbolic acid, oxyquinoline sulfate, and essential oils.

LABEL, IN PART: "Stanley's N D Medicated Douche Powder."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in an accompanying circular entitled "The Importance of PH" were false and misleading. The statements represented and suggested that the article was effective to aid in restoring and maintaining a healthy condition of the vagina and in the relief of minor irritations of the vagina, whereas the article was not effective for such purposes.

DISPOSITION: October 21, 1949. Default decree of condemnation and destruction.

2948. Misbranding of Wonder Bath and Wonder Cream. U. S. v. Kay Austin (Academy Vita Products Co.). Plea of guilty. Fine, \$500. (F. D. C. No. 24256. Sample Nos. 62848-H, 88192-H.)

INFORMATION FILED: June 17, 1949, District of New Jersey, against Kay Austin, trading as the Academy Vita Products Co., Newark, N. J.

ALLEGED SHIPMENT: On or about May 20 and July 12, 1947, from the State of New Jersey into the States of California and New York.

PRODUCT: Analysis disclosed that the *Wonder Bath* consisted of crystals of magnesium sulfate (epsom salt), interspersed with free sulfur, and having a strong odor of pine, and that the *Wonder Cream* consisted essentially of water, methyl salicylate, sodium stearate, and free stearic acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "relax while reducing" appearing on the label of the *Wonder Bath* was false and misleading. The statement represented and suggested that the *Wonder Cream* and the *Wonder Bath* in combination would be efficacious to cause the user to lose weight, whereas the articles would not be efficacious for that purpose.

DISPOSITION: December 16, 1949. A plea of guilty having been entered, the court imposed a fine of \$500.

2949. Misbranding of Roll-A-Ray (device). U. S. v. 133 Cartons * * *.
(F. D. C. No. 26948. Sample No. 8623-K.)

LIBEL FILED: March 23, 1949, Eastern District of New York.

ALLEGED SHIPMENT: On or about February 11, 1948, by the O. A. Sutton Corp., from Wichita, Kans., to New York, N. Y., and thereafter on or about November 10, 1948, to Long Island City, N. Y.

PRODUCT: 133 cartons each containing 1 *Roll-A-Ray* (device) at Long Island City, N. Y. Examination showed that the device consisted of a brown plastic molded case with handle attached. The case enclosed a light bulb and two rubber rollers placed at either end of the bottom part of the case. The rollers would contact the body for massaging purposes, and the light bulb would furnish heat. A plastic grid was fitted over the bulb to protect the body from contact with the lamp.

LABEL, IN PART: (Carton) "Roll-A-Ray Heat Massage With Infra Red."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading since heat and massage are not adequate treatments for such purposes: "For Home Reducing and an Aid in the Relief of Discomforts Arising from Rheumatism, Lumbago, Muscular Aches, Physical Aches * * * for Health and Beauty * * * to remove fatty tissues. Many varied ailments respond to application of heat and massage * * * for loosening muscles and assisting in driving fatty tissues away."

DISPOSITION: December 19, 1949. The Elcord Products Corp., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling, under the supervision of the Federal Security Agency. The court further ordered that the devices should be modified by removing the 60-watt bulb contained therein and replacing it with a 30-watt bulb; by placing foil reflectors on the inner portions of the devices; by covering, removing, or destroying the labeling indicating directions and uses borne on the sides of the cartons in which the devices had been packed; and by using a carton cover and labeling approved by the Food and Drug Administration.

2950. Misbranding of Roll-A-Ray (device). U. S. v. 23 Cartons * * *.
(F. D. C. No. 26949. Sample No. 10961-K.)

LIBEL FILED: March 24, 1949, District of Connecticut.

ALLEGED SHIPMENT: On or about November 3, 1948, by the Electric Cord Co., from New York, N. Y.

PRODUCT: 23 Cartons each containing 1 *Roll-A-Ray* (device) at Hartford, Conn.

NATURE OF CHARGE: Misbranding, Section 502 (a), the device was misbranded in the same respect as the device reported in the preceding notice of judgment, No. 2949.

DISPOSITION: November 15, 1949. Default decree of condemnation and destruction.

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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2951-2970

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C. May 10, 1950.

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS

2951. Misbranding of *Meta Androgen*, *Meta Lucyton*, and *Ascorbodium*. U. S. v. 45 Bottles, etc. (F. D. C. No. 27813. Sample Nos. 55185-K, 55186-K, 55189-K.)

LABEL FILED: September 6, 1949, Western District of Oklahoma.

ALLEGED SHIPMENT: By Dan Coombs, from Kansas City, Mo. The products were shipped on or about June 15, 1948, and February 5 and March 13, 1949; and certain printed matter was shipped in February 1948, and at various times thereafter.

PRODUCT: 45 150-tablet bottles of *Meta Androgen*, 20 150-tablet bottles of *Meta Lucyton*, and 15 100-tablet bottles of *Ascorbodium* at Oklahoma City, Okla., together with a loose-leaf book entitled "The New Master of Disease," and a page entitled "Meta Androstenedione and Meta Lucyton or Meta Androgen" which had been shipped for insertion in the book. Examination showed that the *Meta Androgen* contained methyltestosterone; that the *Meta Lucyton* contained anhydrohydroxyprogesterone; and that the *Ascorbodium* contained 103 milligrams of ascorbic acid per tablet.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the loose-leaf book and on the uninserted page were false and misleading since the articles were not effective for the purposes stated and implied. The statements represented and suggested:

That the *Meta Androgen* was effective to correct homosexual tendencies; to counteract the male climacteric and functional hypogonadism in middle-aged males; to restore physical and mental vigor and emotional equilibrium; to ameliorate psychic disturbances such as irritability and melancholia; to control insomnia associated with the male climacteric; to increase dynamic and static muscular performances, muscular strength, and resistance of the nervous system against fatigue; to correct the basic causes of most female functional disturbances; to favorably affect the vaginal mucous membrane and its allied secretory glands; to neutralize excess circulating estrogen, thereby removing a disturbing factor in the handling of female disorders; to treat hypogonadism or hypo-eccrisis (defective genitalia secretion) in the female; to treat cardiac cirrhosis; to increase muscular development and sense of well-being with a positive nitrogen balance in pituitary deficiencies; and to build up the uteri to within normal limits;

That the *Meta Lucyton* was effective to aid the development of abnormally small or hypoplastic breasts, whether as the solitary complaint or as part of the general picture of hypogonadism; to treat juvenile vaginitis; to suppress lactation; to prevent nausea and vomiting of pregnancy; and to remove fuzz from the upper lip or other masculine characteristics in a female in cases where the meta androstenedione may have a tendency to increase such characteristics;

That the *Ascorbodium* was effective to treat peripheral vascular disease, coronary thrombosis, inflammation of the blood vessels, Buerger's disease, blocked blood vessels, hay fever, asthma, skin eruptions associated with sensitivity to food, and similar conditions by stimulating histamine synthesis.

Further misbranding, Section 502 (j), the *Meta Androgen* was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, (bottle label) "Place

under tongue for absorption" and (uninserted page) "Directions for the male: 1 pellet under the tongue 4 times daily for a week or 10 days. 1 pellet under the tongue 3 times daily for a week or 10 days. 1 pellet under the tongue 2 times daily for a week or 10 days. 1 pellet under the tongue 1 time daily for a week or 10 days. * * * Directions for the female: Follow the same dosage as for the male until the first evidence of biological urge, or an itching sensation around the clitoris, then drop down to the next step, until 2 weeks after the beginning of the next menses period. Rest two days. On the third day give 1 pellet daily of Meta Lucyton until the beginning of the next menses, when you again give Meta Androstenedione in the same amount as given just before the 2 day rest."

DISPOSITION: October 26, 1949. Default decree of condemnation and destruction.

2952. Misbranding of Orange Blossom Suppositories. U. S. v. 35 Packages
* * *. (F. D. C. No. 27999. Sample No. 57010-K.)

LABEL FILED: September 27, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about August 24, 1949, by the Dr. J. A. McGill Co., from Chicago, Ill.

PRODUCT: 35 packages each containing 6 *Orange Blossom Suppositories* at New York, N. Y. Examination showed that the suppositories consisted essentially of ammonium alum, approximately 50 percent, borax and siliceous material in a fatty base.

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "Directions Remove tinfoil and at bedtime insert one suppository in vagina and with your finger push it up as far as you can. Let it remain there undisturbed for three days. Then at night take a douche of warm water, and on the evening of the second day apply again as above, making the application every five days excepting at monthly periods, allowing four days for the periods, then apply the suppository every five days. The use of *Orange Blossom Suppositories* is not recommended at the menstrual period or during pregnancy."

DISPOSITION: January 16, 1950. Default decree of condemnation. The court ordered that a number of the suppositories be released to the Food and Drug Administration and that the remainder be destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2953. Misbranding of nembital capsules, seconal sodium capsules, and Tuinal capsules. U. S. v. Benet's Pharmacies, Inc., and Harry Benet. Pleas of guilty. Fine, \$2,000. (F. D. C. No. 26706. Sample Nos. 18367-K, 18379-K, 18592-K, 18594-K, 18596-K, 19670-K, 19675-K, 19679-K, 19680-K, 19687-K, 19690-K to 19692-K, incl., 19696-K, 43834-K, 51222-K, 51312-K to 51315-K, incl.)

INFORMATION FILED: August 25, 1949, Southern District of Ohio, against Benet's Pharmacies, Inc., Cincinnati, Ohio., and Harry Benet, president and treasurer of the corporation.

INTERSTATE SHIPMENT: Between the approximate dates of May 6, 1948, and September 9, 1948, from the States of Illinois and Indiana into the State of Ohio, of quantities of *nembital capsules*, *seconal sodium capsules* and *Tuinal capsules*.

ALLEGED VIOLATION: On or about October 18, 19, and 20, and November 16, 17, 18, 29, and 30, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused a number of capsules of the drugs to be repacked and sold to various persons without a physician's prescription, which acts of the defendants resulted in the repackaged drugs being misbranded. The drugs when shipped in interstate commerce, were labeled with the prescription legend required by the regulations.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the labels of the repackaged capsules of the drugs contained no statement of the quantity of the contents. Further misbranding, Section 502 (d), the capsules of the drugs contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as habit forming; and the label of the repackaged capsules of the drugs failed to bear the name and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Sections 502 (e) (1) and (2), the repackaged drugs were not designated solely by names recognized in an official compendium, and the labels of the *seconal sodium capsules* and *nembutal capsules* failed to bear the common or usual name of the drugs, namely, "seconal sodium" and "pentobarbital sodium," respectively; and the label of the repackaged *Tuinal capsules* failed to bear the common or usual name of each active ingredient, namely, "seconal sodium" and "amytal sodium." Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules of the drugs failed to bear adequate directions for use since the directions for use "One at bedtime as directed" and other directions similarly worded, borne on the labeling of the repackaged capsules, were not adequate directions for use.

DISPOSITION: October 5, 1949. Pleas of guilty having been entered, the court imposed against the defendants, jointly, a fine of \$100 on each of the twenty counts of the information.

2954. Misbranding of seconal sodium capsules, nembutal capsules, and Tuinal capsules. U. S. v. Alvin A. Bredemeyer (Madison Place Pharmacy). Plea of guilty. Fine, \$700. (F. D. C. No. 26720. Sample Nos. 19669-K, 19693-K, 19700-K, 43836-K, 43844-K to 43846-K, incl.)

INFORMATION FILED: August 25, 1949, Southern District of Ohio, against Alvin A. Bredemeyer, trading as the Madison Place Pharmacy, Cincinnati, Ohio.

INTERSTATE SHIPMENT: On or about May 13, 1947, from North Chicago, Ill., to Cincinnati, Ohio, of a quantity of *nembutal capsules*, and between the approximate dates of August 8, 1947, and September 29, 1948, from Indianapolis, Ind., into Cincinnati, Ohio, of quantities of *seconal sodium capsules* and *Tuinal capsules*.

ALLEGED VIOLATION: On or about October 18 and 19 and November 8, 18, 26, 29, and 30, 1948, while a number of the capsules were being held for sale after shipment in interstate commerce, the defendant caused a number of capsules of the drugs to be removed from the bottles in which they had been shipped and to be repacked and sold to various persons without a prescription, which acts of the defendant resulted in the capsules being misbranded. When the drugs were shipped in interstate commerce, they bore on their labels the prescription legend prescribed by the regulations.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules bore no labels containing statements of the quantity of the contents. Further misbranding, Section 502 (d), the repackaged capsules contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as habit forming; and the labels of the repackaged capsules failed to bear the names and quantities or proportions of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (e) (1), the labels of the repackaged *seconal sodium capsules* and *nembutal capsules* failed to bear the common or usual names of the drugs, namely, "seconal sodium" and "pentobarbital sodium"; Section 502 (e) (2), the label of the repackaged *Tuinal capsules* failed to bear the common or usual names of each active ingredient, namely, "seconal sodium" and "amytal sodium"; and, Section 502 (f) (1), the directions for use, namely, (*seconal sodium capsules* and *nembutal capsules*) "One (1) capsule at bedtime as directed" and (*Tuinal*) "As directed," borne on the labeling of the repackaged capsules of drugs, were not adequate directions for use.

DISPOSITION: October 5, 1949. A plea of guilty having been entered, the court imposed a fine of \$700.

2955. Misbranding of seconal sodium capsules, Tuinal capsules, and nembutal capsules. U. S. v. Tischbein Apothecary, Inc., and Louis Tischbein. Pleas of guilty. Fine of \$800 against defendants jointly. (F. D. C. No. 26721. Sample Nos. 19674-K, 19678-K, 19689-K, 19695-K, 44213-K, 44214-K, 51307-K, 51316-K.)

INFORMATION FILED: August 25, 1949, Southern District of Ohio, against Tischbein Apothecary, Inc., Cincinnati, Ohio, and Louis Tischbein, president of the corporation.

INTERSTATE SHIPMENT: Between the approximate dates of October 16, 1947, and November 18, 1948, from the States of Indiana and Illinois into the State of Ohio.

ALLEGED VIOLATION: On or about October 19 and 20 and November 17, 18, 29, and 30, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused a number of capsules of the drugs to be repacked and sold to various persons without a prescription, which acts of the defendants resulted in the drugs being misbranded. When the drugs were shipped in interstate commerce, they bore on their labels the prescription legend prescribed by the regulations.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing statements of the quantity of the contents; Section 502 (e) (1), the labels of the repackaged *seconal sodium capsules* and *nembutal capsules* failed to bear the common or usual names of the drugs, namely, "seconal sodium" and "pentobarbital sodium"; Section 502 (e) (2), the label of the repackaged *Tuinal capsules* failed to bear the common or usual name of each active ingredient, namely, "seconal sodium" and "sodium amytal." Further misbranding, Section 502 (d), the drugs contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as habit forming; and the labels of the repackaged drugs failed to bear the name and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502

(f) (1), the directions for use, and other directions similarly worded borne on the labeling of the repackaged capsules were not adequate directions for use, namely, "One capsule at bedtime when necessary as directed," "One capsule at bedtime as directed," and "One for rest."

DISPOSITION: October 5, 1949. Pleas of guilty having been entered, the court imposed a fine of \$800 against the defendants jointly.

2956. Misbranding of nembutal capsules and seconal sodium capsules. U. S. v. Harry James Tischbein (Tischbein Apothecary). Plea of guilty. Fine, \$700. (F. D. C. No. 26707. Sample Nos. 18593-K, 18595-K, 18597-K, 19673-K, 19686-K, 51093-K, 51094-K.)

INFORMATION FILED: August 25, 1949, Southern District of Ohio, against Harry James Tischbein, trading as Tischbein Apothecary, Cincinnati, Ohio.

INTERSTATE SHIPMENT: From the States of Illinois and Indiana into the State of Ohio.

ALLEGED VIOLATION: On or about October 18 and 19 and November 16, 17, 29, and 30, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repacked and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded. When the drugs were shipped in interstate commerce, they bore on their labels the prescription legend prescribed by the regulations.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no label containing a statement of the quantity of the contents. Further misbranding, Section 502 (d), the drugs contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (e) (1), the labels of the repackaged drugs failed to bear the common or usual names of the drugs, namely, "seconal sodium" and "pentobarbital sodium"; and, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use since the directions for use on the containers of the repackaged drugs, namely, "One capsule at bedtime if needed as directed," "One at bedtime as needed as directed," "One capsule at bedtime if necessary as directed," and "One at bedtime for sleep," were not adequate directions for use.

DISPOSITION: October 5, 1949. A plea of guilty having been entered, the court imposed a fine of \$700.

2957. Misbranding of nembutal capsules and seconal sodium capsules. U. S. v. Robert Tischbein Pharmacy. Plea of guilty. Fine, \$700. (F. D. C. No. 26705. Sample Nos. 18365-K, 19671-K, 19688-K, 43543-K, 43544-K, 43625-K, 43835-K.)

INFORMATION FILED: August 25, 1949, Southern District of Ohio, against the Robert Tischbein Pharmacy, a partnership, Cincinnati, Ohio.

INTERSTATE SHIPMENT: On or about October 16, 1947, from the State of Illinois into the State of Ohio, of a quantity of *nembutal capsules*, and between September 9 and 29, 1948, from the State of Indiana into the State of Ohio, of a quantity of *seconal sodium capsules*.

ALLEGED VIOLATION: On or about October 18 and 19 and November 17, 18, 29, and 30, 1948, and while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repacked and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded. When the drugs were shipped in interstate commerce, they bore on their labels the prescription legend prescribed by the regulations.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged drugs bore no labels containing a statement of the quantity of the contents; and Section 502 (e) (1), the labels of the repackaged drugs failed to bear the common or usual names of the drugs, namely, "pentobarbital sodium" and "seconal sodium." Further misbranding, Section 502 (d), the drugs contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use since the directions for use on the containers of the repackaged drugs, namely, "One at bedtime for sleep," "One at bedtime as directed," and "One capsule at bedtime as directed," were not adequate directions for use.

DISPOSITION: October 5, 1949. A plea of guilty having been entered, the court imposed a fine of \$700.

2958. Misbranding of nembutal capsules. U. S. v. Parker's Pharmacy and Esther R. Parker. Pleas of guilty. Fine of \$600 against defendants jointly. (F. D. C. No. 26704. Sample Nos. 19677-K, 19681-K, 19694-K, 51301-K, 51304-K, 51311-K.)

INFORMATION FILED: August 25, 1949, Southern District of Ohio, against Parker's Pharmacy, a partnership, Mount Healthy, Ohio, and Esther R. Parker, a partner in the partnership.

INTERSTATE SHIPMENT: On or about August 11 and November 7, 1947, and November 2, 1948, from North Chicago, Ill.

ALLEGED VIOLATION: On or about October 19 and 21 and November 18, 28, and 30, 1948, while the drug was being held for sale after shipment in interstate commerce, the defendants caused a number of capsules of the drug to be removed from the bottles in which it had been shipped, and repackaged the drug and sold it to various persons without a prescription, which acts of the defendants resulted in the repackaged drug being misbranded. When the drug was shipped in interstate commerce, it bore on its label the prescription legend required by the regulations.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules bore no label containing a statement of the quantity of the contents. Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (e) (1), the label of the repackaged capsules failed to bear

the common or usual name of the drug, namely, "pentobarbital sodium"; and, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use since a portion of the repackaged capsules bore no labeling containing directions for use and since the directions for use on the labeling of the remainder of the repackaged capsules, namely, "One capsule at bedtime when needed," "One capsule at bedtime when necessary," and "one or two at bedtime," were not adequate directions for use.

DISPOSITION: October 5, 1949. Pleas of guilty having been entered, the court imposed a total fine of \$600 against the defendants jointly.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2959. Adulteration of ointment. U. S. v. 62,092 Tubes * * *. (F. D. C. No. 27942. Sample No. 32825-K.)

LABEL FILED: October 28, 1949, Northern District of California.

ALLEGED SHIPMENT: Between June 6, 1947, and May 13, 1949, from Cleveland, Ohio.

PRODUCT: 62,092 1½-ounce tubes of *ointment* at Berkeley, Calif. Examination disclosed that a material proportion of the product was decomposed, as evidenced by the dry and granular condition of the *ointment*, discoloration of the *ointment*, and corrosion of the tubes.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a decomposed substance. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 20, 1949. Default decree of condemnation and destruction.

2960. Adulteration of orange peel. U. S. v. 37 Bags * * *. (F. D. C. No. 28247. Sample No. 10068-K.)

LABEL FILED: November 3, 1949, Southern District of New York.

ALLEGED SHIPMENT: In May 1945, from Haiti.

PRODUCT: 37 41-pound bags of *orange peel* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 19, 1949. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

2961. Action to enjoin and restrain the interstate shipment of various drugs. U. S. v. Cowley Pharmaceuticals, Inc. Preliminary injunction denied. (Inj. No. 186.)

COMPLAINT FILED: February 26, 1948, District of Massachusetts, against Cowley Pharmaceuticals, Inc., Worcester, Mass.

NATURE OF CHARGE: The defendant had been, and at the time of filing the complaint was, shipping in interstate commerce certain drugs which were adulterated and misbranded in the following respects:

Niacinamide tablets, sulfathiazole tablets, vitamin B₁ tablets, quinine sulfate tablets, phenobarbital tablets, and ferrous sulfate tablets, drugs the names of which are recognized in the United States Pharmacopoeia. Adulteration, Section 501 (b), the strength of each of the drugs differed from the standard set forth in the United States Pharmacopoeia, in that the *ferrous sulfate tablets* contained more than the maximum quantity of ferrous sulfate permitted by that compendium, and the remaining tablets of the drugs contained less of the labeled drug than the minimum quantity prescribed by that compendium. Misbranding, Section 502 (a), the label statements declaring the quantity of each of the drugs contained in the various tablets were false and misleading.

A P C Compound Pink Tablets, ephedrine with phenobarbital tablets, and calcium gluconate C T tablets, drugs not recognized in an official compendium. Adulteration, Section 501 (c), their strength differed from that which they were represented to possess on their labels since the *A P C Compound Pink Tablets* contained more acetophenetidin than the labeled amount; the *ephedrine with phenobarbital tablets* contained less ephedrine and more phenobarbital than the labeled amount; and the *calcium gluconate C T tablets* contained less calcium gluconate than the labeled amount. Misbranding Section 502 (a), the statements, "Each tablet contains: * * * acetophenetidin 2 grs." on the label of the *A P C Compound Pink Tablets*, "Each tablet contains Calcium Gluconate 1 gm." on the label of the *calcium gluconate C T tablets*, and "Each tablet contains Ephedrine $\frac{3}{8}$ gr. Phenobarbital $\frac{1}{2}$ gr." on the label of the *ephedrine with phenobarbital tablets*, were false and misleading.

Thyroid tablets. Misbranding, Section 502 (a), the label statement "Tablets * * * Thyroid U. S. P." was false and misleading since the statement represented that the product consisted solely of desiccated thyroid, as required by the standard set forth in the United States Pharmacopoeia, whereas the article consisted of desiccated thyroid and diiodo hydroxyquinoline, or desiccated thyroid and phenacetin and salol.

Soda mint tablets. Misbranding, Section 502 (a), the label statements "Soda Mint Tablets" and "Each tablet contains Sodium Bicarbonate * * * flavored with mint" were false and misleading since the product contained aspirin, and the label failed to declare the presence of aspirin.

The complaint alleged further that the defendant had shipped in interstate commerce certain foods which were adulterated and misbranded, as set forth in notices of judgment on foods.

PRAYER OF COMPLAINT: That the defendant be perpetually enjoined from commission of the acts complained of, and that a preliminary injunction be granted during the pendency of the action.

DISPOSITION: On March 30, 1948, at the conclusion of the hearing on the Government's motion for a preliminary injunction, the court handed down findings of fact and a conclusion of law, and on April 2, 1948, entered an order denying the Government's prayer for a preliminary injunction. The findings of fact, conclusion of law, and discussion follow:

HEALEY, *District Judge*:

FINDINGS OF FACT

"1. The respondent, Cowley Pharmaceuticals, Inc., is a Massachusetts Corporation having its principal place of business in Worcester, Massachusetts.

"2. The respondent is and has been engaged in the manufacture and sale of various articles of drug and articles of food, a large quantity of which are sold and shipped in interstate commerce.

"3. The government has submitted evidence that on various dates during the period from June 4, 1946, to November 2, 1947, the respondent, in violation of 21 USCA Sec 331 (a), shipped in interstate commerce certain articles of drug as defined by 21 USCA 321 (g) (1), (2), and (3), and certain articles of food as defined by 21 USCA Sec 321 (f) (1) which were allegedly adulterated and misbranded, in the particulars stated in Exhibit A appended to the complaint.

"4. In all cases but one, the product is allegedly adulterated and misbranded because it allegedly contained a different quantity of some constituent part than was stated on the label. In the case of the soda mint tablets, it is alleged that they contained aspirin, the presence of which was not disclosed on the label.

"5. There is no evidence that any inspection of respondent's factory has been made by any agent of the Food and Drug Administration since October 1, 1947.

"6. There is no evidence that any adulterated or misbranded articles of drug or food have been shipped in interstate commerce by the respondent since the shipment made on November 2, 1947.

"7. By his affidavits, Benjamin C. Cowley, president and treasurer of the respondent, states that he has adopted the recommendations made by the government agents and inspectors regarding improvements in respondent's factory, facilities and methods of manufacture so as to eliminate the probability of any future violations of the Act.

DISCUSSION

"The purpose of the Federal Food, Drug, and Cosmetic Act is to protect the consuming public, *United States v. Lord-Mott Company*, 57 F Supp 128; *United States v. Crown Rubber Sundries Company*, 67 F Supp 92; *Federal Security Administrator v. Quaker Oats Company*, 318 US 218, and the Act is sufficiently broad to allow the issuance of an injunction even though no wilfulness or knowledge on the part of the respondent or its agents is shown. *United States v. Greenbaum*, 138 F (2d) 437.

"However, in my opinion, a preliminary injunction should not issue unless the government makes out a case where there is a strong probability that the respondent's allegedly illegal acts will continue in the future.

"In the instant case, the complaint was filed on February 26, 1948, more than three months after the last alleged violation of the Act, and almost five months after the last inspection of respondent's premises by the government agents. In the light of the affidavits presented by the respondent containing statements that the causes for any possible violations have been eliminated, and in the absence of any evidence of recent violations, there is not sufficient evidence of the probability of any future violations to warrant the issuance of a preliminary injunction as prayed for.

CONCLUSION OF LAW

"The complainant has not produced sufficient evidence of the probability of future violations of the Act by the respondent to warrant the issuance of a preliminary injunction."

2962. Adulteration and misbranding of estrogenic substance in oil and Gynestrin estrogenic hormones, and misbranding of Obenoids. U. S. v. Pro-Medico Laboratories, Inc., and Samuel Heller. Pleas of nolo contendere. Corporation fined \$900; individual defendant fined \$9 and placed on 6 months' probation. (F. D. C. No. 17879. Sample Nos. 3826-H, 3905-H, 6708-H, 6709-H, 20195-H.)

INDICTMENT RETURNED: December 9, 1947, Eastern District of New York, against Pro-Medico Laboratories, Inc., Brooklyn, N. Y., and Samuel Heller, director.

ALLEGED SHIPMENT: Between the approximate dates of December 8, 1944, and March 6, 1945, from the State of New York into the States of Pennsylvania, Connecticut, and Oklahoma.

LABEL, IN PART: "A Pro-Medico Product 3,500 cc Estrogenic Substance in Oil Each cc contains Estrogenic Substance derived from equine urine," "Estrogenic Hormones Multiple Dose Vial A sterile solution in ampul oil of estrogenic substances derived from equine urine * * * Manufactured for The Vale Chemical Co., Inc. Allentown, Penna.," "Gynestrin Estrogenic Hormones An oil solution of estrogenic hormones, derived from equine urine," and "Obenoids - Pink Each Tablet Contains—Phenobarbital $\frac{1}{4}$ grain."

NATURE OF CHARGE: *Estrogenic substance.* Adulteration, Section 501 (d), estrogenic substance other than as it naturally occurs in and is extracted from equine urine and containing little or no estrone, had been substituted for estrogenic substance as it naturally occurs in and is extracted from equine urine, which the product purported and was represented to be. Misbranding, Section 502 (a), the label statement "Estrogenic Substance derived from equine urine" was false and misleading.

Gynestrin estrogenic hormones. Adulteration, Section 501 (d), estrogenic hormones other than as they naturally occur in and are extracted from equine urine, had been substituted for estrogenic hormones as they naturally occur in and are extracted from equine urine, which the product purported and was represented to be. Misbranding, Section 502 (a), the label statement "Estrogenic Hormones derived from equine urine" was false and misleading.

Obenoids. Misbranding, Section 502 (a), the label statement "Contains—Phenobarbital" was false and misleading since the product contained no phenobarbital; and, Section 502 (e) (2), the product was not sold under a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the name and quantity and proportion of atropine that it contained.

DISPOSITION: On March 1, 1949, a motion by the defendant for a bill of particulars was granted to the extent of requiring the Government to state how many International Estrone Units per cubic centimeter were contained in the estrogenic substance in oil referred to in counts 1 and 3 of the indictment. On December 12, 1949, pleas of nolo contendere were entered and the corporation was fined \$900, and the individual defendant was fined \$9 and placed on probation for 6 months.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2963. Misbranding of Nue-Ovo. U. S. v. 24 Units * * * (and 12 other seizure actions). Cases consolidated and tried to the court. Government's motion for summary judgment granted. Decree of condemnation and destruction. (F. D. C. Nos. 24649, 24709, 24728, 24840, 24850, 24859, 24874, 24891, 24894, 24895, 24908, 24909, 25101. Sample Nos. 14542-K, 27743-K, 28167-K, 28529-K, 28564-K, 28983-K, 29337-K, 31354-K, 36794-K, 37343-K, 37615-K, 40523-K, 40622-K, 40624-K.)

*See also Nos. 2951, 2961, 2962.

LIBELS FILED: Between April 21 and July 16, 1948, Eastern and Western Districts of Washington, District of Kansas, Northern District of Illinois, District of Colorado, Southern District of California, Eastern and Western Districts of Missouri, and District of Utah.

ALLEGED SHIPMENT: Between the approximate dates of December 31, 1947, and June 10, 1948, by Research Laboratories, Inc., from Portland, Oreg.

PRODUCT: Nue-Ovo. 117 units, each containing 3 bottles; 24 cases, each containing 6 cartons of 3 bottles each; 7 cases, each containing 18 bottles; and 9 cartons and 57 bottles, at Seattle and Pasco, Wash.; La Crosse, Kans.; Chicago, Ill.; Denver, Colo.; Vernon, Calif.; St. Louis and Kansas City, Mo.; and Salt Lake City, Utah.

LABEL, IN PART: (Bottle) "Nue-Ovo * * * Active Ingredients: An aqueous extraction of Plume Thistle, Burdock, Quassia, Sage, Cinnamon, Horehound, Ginseng, Calamus, Dandelion, Althea, Kola Nut, Sodium Salicylate, Cascara, Licorice, Vitamin B₁."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in leaflets entitled "Information on Nue-Ovo" accompanying one shipment of the article and the statement "Nue-Ovo for Rheumatism and Arthritis" appearing on the shipping case labels of the other shipments of the article were false and misleading. The statements represented and suggested that the article was effective in the treatment of rheumatism and arthritis, whereas the article was not effective in the treatment of those conditions.

DISPOSITION: The libel proceedings having been consolidated for purposes of trial in the Northern District of Illinois, and Research Laboratories, Inc., having appeared as claimant, the matter came on for hearing before the court on the Government's motion for a summary judgment. On October 11, 1949, after considering the arguments of counsel and briefs filed in support of and against the motion, the court handed down the following decision:

CAMPBELL, District Judge:

"This is a consolidation of six cases, all involving the same subject matter. The proceedings are brought pursuant to libels alleging misbranding, under 21 U. S. C. A. 352 (a), of a certain product known as Nue-Ovo, which is manufactured by the claimant, Research Laboratories, Inc. In all cases but one the shipping case label bears the statement 'Nue-Ovo for Rheumatism and Arthritis.' In the remaining case, circulars entitled 'Information on Nue-Ovo,' which were shipped with the article, bear the statement 'Nue-Ovo * * * to be used in the treatment of Arthritis and Rheumatism.' It is the contention of the Government that the statement in each case is false and misleading, in that its ultimate effect is to represent and suggest that the article is effective in the treatment of arthritis and rheumatism, whereas the article is not so effective.

"Libellant now moves for summary judgment on the basis of estoppel by judgment, i. e., that judgments have previously been rendered in favor of the libellant in the United States District Court of the Western District of Washington in the case of United States of America vs. 143 Packages, more or less, each containing 3 bottles of 'Nue-Ovo' (1943), and in the case of United States of America vs. 600 units, more or less, each containing 3 bottles of 'Nue-Ovo' (1946). The latter judgment was affirmed in 167 F. 2d 410; certiorari denied 335 U. S. 843. Claimant opposes the motion on the ground that different issues of law and fact exist in the present cases.

"Although the claimant admits the wording set forth on the shipping cases and circulars, it cites the language of the back bottle label in support of its contention:

IMPORTANT

Many users believe NUE-OVO has brought them relief, but experts differ as to its merits. It is prescribed by some doctors although not generally accepted by the medical profession. If it does not relieve you after a fair trial in accordance with the directions, discontinue its use. Any guarantee to induce the purchase of NUE-OVO is unauthorized.

"It is claimant's position, therefore, that the present consolidated actions present the issues of whether (1) the labeling represents that there is a difference of medical opinion as to the effectiveness of the product in the treatment of arthritis and rheumatism, and (2) there is in fact such a difference of medical opinion, whereas in the previous actions it had only to be determined whether the product was represented to be effective in the treatment of those diseases and whether it was so effective.

"Claimant's argument is untenable. In effect, the supposedly new issues were presented to and disposed of by the Court of Appeals of the Ninth Circuit in *Research Laboratories vs. United States*, 167 F. 2nd 410:

Summarized, the appellant's attacks upon the judgment below are as follows:

1. The court below erred in submitting issues to the jury, since every statement in the labeling as to the effectiveness of the product is a statement of opinion, and at the conclusion of the case the record showed nothing more than a difference of opinion among qualified experts as to the effectiveness of the product.

However, the Court of Appeals concluded that the evidence adduced at the trial went beyond a mere expression of difference in medical opinion, and that the jury could and did properly decide that the opinions presented by the claimant's witnesses were to be rejected. The rule has been most lucidly stated in *U. S. vs. 7 Jugs, etc.*, of *Dr. Salsbury's Rakos*:

... If the evidence is such that it appears that the question of effectiveness has not transcended the realm of demonstrable fact, the court must hold as a matter of law that assertions of effectiveness are not false and refuse to submit the question to the jury. *American School of Magnetic Healing vs. McAnnulty*, supra; see *L. B. Silver Co. vs. Federal Trade Commission*, 6 Cir., 1923, 289 F. 985; cf. *Bruce vs. United States*, 8 Cir., 1912, 202 F. 98. But where the evidence indicates that there is a standard of demonstrable truth and fact by which the jury can measure the claims of effectiveness, the court should then submit the question to the jury under appropriate instructions. What the evidence shows in a given case is a question of law for the court to decide. * * * * *

... Certainly, where factual proof is present which indicates the worthlessness of the remedies in question, mere injection of an alleged difference of opinion on the part of persons whom the jury might find were either ignorant or charlatans, could not operate to prevent the jury from deciding the question of effectiveness. Under the evidence in this case, the jury was entirely warranted in finding that the contrary expressions of opinion by the witnesses appearing for claimant were in direct opposition to established scientific fact.

"Since, therefore, the juries in the previous cases determined that the product was ineffective in the treatment of arthritis and rheumatism, they must necessarily have rejected as valueless the testimony of the witnesses appearing on behalf of the claimant. In other words, a finding that there was not an honest difference of opinion as to effectiveness, was an essential ingredient of the conclusion that the product was ineffective. Furthermore, the quality of the testimony would not be altered here, in view of claimant's offer to stipulate that the same medical and lay witnesses as were produced by claimant and libellant in the case of *U. S. vs. 600 Units, etc.*, supra, would testify to the same extent in the instant case.

"It still remains, however, to be decided whether all issues presented in this litigation are *res judicata*. The doctrine was ably defined in *Henderson vs. United States Radiator Corp.*, 78 F. 2nd 674:

The doctrine of *res judicata* embodies two main rules which may be stated as follows:

(1) The final judgment or decree of a court of competent jurisdiction upon the merits concludes the parties and their privies to the litigation, and constitutes a bar to a new action or suit upon the same cause of action either before the same or any other tribunal.

(2) Any right, fact or matter in issue and directly adjudicated, or necessarily involved in the determination of an action before a competent court in which a judgment or decree has been rendered upon the merits, is conclusively settled by the judgment therein and cannot again be litigated between the same parties and their privies, whether the claim, demand, purpose or subject-matter of the two suits is the same or not.

The principle of the first rule is referred to as "bar by former judgment," and the second as "conclusiveness of judgment."

Each of the articles involved in these consolidated cases bears an identical label. This label lists the ingredients as follows: 'An aqueous extraction of *Plume Thistle, Burdock, Quassia, Sage, Cinnamon, Horehound, Ginseng, Calamus, Dandelion, Althea, Kola Nut, Sodium Salicylate, Cascara, Licorice, Vitamin B.*' These ingredients are identical with the ingredients of the article which was involved in three and part of the fourth of the cases consolidated in *U. S. vs. 600 Units, etc.* These ingredients are also essentially the same as the ingredients of the article involved in the other part of the fourth case in the

above case and in *U. S. vs. 143 Packages, etc.* This element, combined with the determinations, both direct and necessarily implied, of the juries in the previous cases as to effectiveness, clearly brings the instant action within the doctrine of *res judicata* as enunciated in the *Henderson case, supra*.

"The entire history of the manufacture and sale of *Nue-Ovo* is marked by questionable promotional methods. This most recent mode of labeling is merely another subtle maneuver adopted for the purpose of avoiding the dictates of the Food and Drugs Act and inducing a gullible public to purchase a worthless product for the cure of rheumatism and arthritis. The language of *U. S. vs. 95 Barrels of Vinegar, 265 U. S. 438*, equally well describes the activities of the claimant in the instant action:

The statute is plain and direct. Its comprehensive terms condemn every statement and device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the act.

"Accordingly, therefore, the Government's motion for summary judgment is granted. The Government is hereby directed to submit to the Court, within 15 days, a form of judgment and a form of decree of forfeiture and condemnation."

On November 16, 1949, in accordance with the above decision, a decree was entered providing for condemnation and destruction of the product.

2964. *Misbranding of Remin's Brewers' Hydrolyzed Yeast Powder, Remin's Multi-Vitamin A-B-C-D Drops, Remin's Brewers' Hydrolyzed Yeast and Whey Powder, and Remin's (Powdered) Hydrolyzed Brewers' Yeast Vegetables and Whey.* *U. S. v. Eugene A. Kazmark (M & M Service).* Plea of guilty. Fine, \$10. (F. D. C. No. 25624. Sample Nos. 16849-K to 16852-K, incl.)

INFORMATION FILED: August 4, 1949, Northern District of Illinois, against Eugene A. Kazmark, trading as M & M Service, at Joliet, Ill.

ALLEGED SHIPMENT: On or about April 13, 1948, from the State of Illinois into the State of Wisconsin.

LABEL, IN PART: "Remin's Brewers' Hydrolyzed Yeast (Powder) A Supplementary source of Hydrolyzed Brewers' Yeast and its natural vitamins B₁ and B₂," "Remin's Multi-Vitamin A-B-C-D Drops In A Base Of Brewers' Yeast Extract," "Remin's Brewers' Hydrolyzed Yeast and Whey Powder A Supplementary source of Hydrolyzed Brewers' Yeast and its natural vitamins B₁ and B₂," and "Remin's (Powdered) Hydrolyzed Brewers' Yeast Vegetables and Whey."

NATURE OF CHARGE: *Remin's Brewers' Hydrolyzed Yeast Powder, Remin's Brewers' Hydrolyzed Yeast and Whey Powder, and Remin's (Powdered) Hydrolyzed Brewers' Yeast Vegetables and Whey.* Misbranding, Section 502 (a), certain statements in booklets and in a leaflet accompanying the articles were false and misleading since the articles would not be efficacious for the purposes, and would not fulfill the promises, of benefit stated and implied. The booklets were entitled "Remin's * * * Descriptive Price List," "Facts About Vitamins, Amino Acids and Hydrolysates," "Keep in Step with the March of Progress," and "For Protein Vitality Try Remin's Hydrolyzed Yeast," and the leaflet was entitled "Miracle Cure Laid to Diet." The false and misleading statements in the booklets and in the leaflet represented and suggested that the articles would be efficacious in the cure, mitigation, treatment, and prevention of fatigue, sleeplessness, nervousness, neuritis, poor appetite, loss of strength, constipation, and skin disorders; that the articles would be efficacious in the prevention of poliomyelitis (infantile paralysis),

sterility in the male, baldness, great disturbance in the menstrual cycle in the woman, sex gland deterioration, malformation of tooth enamel, and cataracts of the eye; that they would be efficacious in the prevention of an upset in the reproductive cycle in women; that they would be of value to the nervous system; that they would be efficacious in preserving the integrity (health) of the liver and in preventing damage to the liver; that they would be efficacious in old age to maintain nitrogen balance where there is inadequate gastric and pancreatic secretion, impaired absorption, and other gastrointestinal disorders; that they would aid in preventing nutritional edema and be of help in hemoglobin regeneration in cases of nutritional anemia; that they would help increase the gamma globulin in serum protein and would be efficacious in increasing resistance to infections; that they would help to assure adequate protein intake during pregnancy and lactation; that they would be efficacious in the treatment of severe burn cases, fracture, and dislocation; that for patients with gastric ulcers, the articles would be efficacious for the repair of damaged tissue and to speed healing; that the articles would be efficacious in preventing hypoproteinemia, in speeding tissue repair and recovery from operations, in restoring degenerate tissue caused by disease and reflex atrophy, and in the treatment of loss of blood, severe wounds, and bleeding ulcers; that they would help to maintain a positive nitrogen balance in cases of severe diarrhea; that they would be efficacious in the cure, mitigation, and treatment of glandular disorders and infections, simple anemia, pernicious anemia, halitosis (bad breath), cancer, cirrhosis and cirrhotic conditions, acne, pimples, dry skin, diabetes, and glossitis; that they would be efficacious in the cure, mitigation, treatment, and prevention of arthritis and colds; that they would be efficacious in the prevention of cataracts; that they would be efficacious in checking the appetite for alcohol; that the articles, plus copper and the enzyme, tyrosinase, would aid in relieving the condition of malnutrition which has as one of its symptoms the premature graying of the hair; that the articles would aid nature in the postponement of old age; that they would be efficacious in protecting one against overweight; that they would improve the assimilation of food by the undernourished; that they would build up tissues; that each article was essentially a potent normalizing agent; that the articles would be efficacious in the cure, mitigation, and treatment of stomach ulcers and of tumors; that they would be efficacious in maintaining normal health and in changing abnormal to normal conditions; that they would promote nutrition of the reproductive organs and contraction of the muscles; that they would be efficacious in counteracting cancer; that they would promote growth and the formation of red blood corpuscles, protect vitamin C from destruction, and be efficacious in the cure, mitigation, treatment, and prevention of nausea, dizziness, and ear damage; that each article was a special detoxifying agent; that the articles would protect against liver cirrhosis, enable an excess of one amino acid to be converted into others more needed at the moment, and aid in destroying the allergic poison, histamine; that they would retard destruction of vitamin C, counteract nicotine poisoning, and increase vitamin C in the tissues; that each article was an effective detoxifying agent for indole and other poisons found in arthritic conditions; that each article was a powerful detoxifying agent; that the articles would promote glycogen (energy sugar) formation and would aid in gastric secretion and in the prevention of anemia; that each article was a good detoxifying agent, especially for excess sex hormones which would otherwise favor cancer formation; that the articles would be efficacious in

the formation of cartilage, and in the cure, mitigation, treatment, and prevention of allergy, pregnancy difficulties, hay fever, and asthma; that they would aid the liver in the formation of glycogen; that they would be efficacious in the formation of hemoglobin, in the production of antibodies against infection, and in counteracting rancidity in fats; that they would be efficacious in the formation of blood, development of membrane cells, and production of thyroid hormone and adrenaline; that they would provide resistance against disease; that they would be effective in the cure, mitigation, and treatment of ailments from the common cold to serious heart infection; that each article was a general cure for all poisonous conditions of the body cells however caused; that the articles would be efficacious in the control of gastric ulcers; that they would be effective in the cure, mitigation, treatment, and prevention of pneumonitis, rheumatic fever, asthma, rheumatic arthritis, emphysemá, coronary sclerosis, arteriosclerosis, pernicious anemia, and most infections under the common cold; that they would assure one of protein vitality and provide sufficient heat and energy for normal needs; that they would be of value where the natural digestion is not working correctly; that they would be efficacious in the cure, mitigation, and treatment of many disorders of the body; that they would help insure against malnutrition and hypoproteinemia in childhood; and that they would be of benefit to persons who are only able to absorb or assimilate a portion of the proteins which they actually consume every day.

Remin's Multi-Vitamin A-B-C-D Drops. Misbranding, Section 502 (a), certain statements in booklets entitled "Remin's * * * Descriptive Price List 1947" and "Facts About Vitamins, Amino Acids and Hydrolysates," accompanying the article, were false and misleading. The statements represented and suggested that the article would be efficacious in the cure, mitigation, treatment, and prevention of fatigue, sleeplessness, nervousness, neuritis, poor appetite, loss of strength, constipation, and skin disorders; that it would aid in building up resistance against colds and would improve a sense of nutritional well-being; that it would be efficacious in the prevention of poliomyelitis (infantile paralysis); and that it would be efficacious in preserving the integrity (health) of the liver and in preventing damage to the liver. The article would not be efficacious for these purposes and would not fulfill the promises of benefit stated and implied.

The articles were alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: September 19, 1949. A plea of guilty having been entered, the court imposed a fine of \$10.

2965. Misbranding of Whitmer's Black Diamond Liniment, Whitmer's Eureka, and Whitmer's Red Carminative. U. S. v. The H. C. Whitmer Co., Inc. Plea of guilty. Fine, \$500. (F. D. C. No. 26693. Sample Nos. 19438-K, 19441-K, 19442-K, 44020-K.)

INFORMATION FILED: June 2, 1949, Southern District of Indiana, against the H. C. Whitmer Co., Inc., Columbus, Ind.

ALLEGED SHIPMENT: On or about April 5, 19, and 24, 1948, from the State of Indiana into the States of Ohio and Kentucky.

LABEL, IN PART: "Whitmer's Black Diamond Liniment * * * Active Ingredients: Turpentine Fractions, Linseed Oil, Camphor, Pine Oil," "Whitmer's Eureka Alcohol 15% * * * Active Ingredients: Buchu, Uva Ursi, Culver Root, Juniper Berries, Alexander Senna, Caraway Seed, Gentian Root,

Cape Aloe, Hydrangea, Soda Benzoate, Soda Acetate," and "Whitmer's Red Carminative Alcohol 15% * * * Active Ingredients: Red Pepper, Gum Camphor, Oil Cloves, Oil Cinnamon, Carbonate Soda, Yellow Root, Sage, Licorice Root, Raspberry Leaves, Dandelion Root."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles, which included circulars entitled "Whitmer's Black Diamond Liniment," "Whitmer's Eureka," and "Whitmer's Red Carminative," which accompanied the respective products, were false and misleading since the products would not be effective for the purposes claimed.

The false and misleading statements in the labeling represented and suggested:

That *Whitmer's Black Diamond Liniment* would be efficacious in the cure, mitigation, treatment, and prevention in man of wounds, burns, sprains, frost bites, itching, wry neck, and sores which follow injuries: that it would be efficacious to relieve in man the pain and soreness of wounds and to reduce in man the inflammation of wounds: and that it would be efficacious in the cure, mitigation, and treatment in animals of sore shoulders, sprains, bruises, wounds, all lumps and enlargements, nail wounds, and greased heel;

That *Whitmer's Eureka* would be efficacious in the treatment of catarrh of the urinary tract, especially acute cystitis; that the article would have a special effect on the liver; that it would be efficacious in the treatment of inflammatory conditions of the urinary organs, chronic constipation, and atonic conditions of the lower bowel; that it possessed a direct tonic action; that it would encourage a restoration toward normal conditions; that it was a stimulant to the gastric digestion; and that it would be efficacious in the treatment of atonic dyspepsia and similar complaints, chronic disorders of the genito-urinary tract, catarrhal conditions of the bladder and urinary passages, acidosis, and excessive acidity of the urine;

That *Whitmer's Red Carminative* would be efficacious for the relief of menstrual pains, and that it would be efficacious in the cure, mitigation, and treatment of sour stomach.

DISPOSITION: October 25, 1949. A plea of guilty having been entered, the court imposed a fine of \$500.

2966. Misbranding of Miracle Oil and Miracle Inhalers. U. S. v. Irving Gartman (Sandy Sales Co.). Plea of guilty. Fine, \$300. (F. D. C. No. 26735. Sample No. 44341-K.)

INFORMATION FILED: September 16, 1949, Southern District of Ohio, against Irving Gartman, trading as the Sandy Sales Co., Columbus, Ohio.

INTERSTATE SHIPMENT: Between the approximate dates of November 18, 1948, and January 7, 1949, from New York, N. Y., to Columbus, Ohio.

LABEL, IN PART: (Bottles) "Miracle A combination of Oil of Miracle, Oil of Eucalyptus, Oil of camphor, menthol, Oil of peppermint, thymol * * * Distributors Sandy Sales Co. * * * Cleveland 20, Ohio"; (inhalers) "Miracle Inhaler."

ALLEGED VIOLATION: On or about January 14, 1949, while the *Miracle Oil* and the *Miracle Inhalers* were being held for sale after shipment in interstate commerce, the defendant caused various posters to accompany the articles, which acts of the defendant resulted in the articles being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the posters were false and misleading. The statements represented and suggested that the *Miracle Oil* and the *Miracle Inhaler* in combination with each other would be efficacious in the cure, mitigation, and treatment of head colds, hay fever, arthritis, earache, sinus trouble, rose fever, neuritis, chest colds, asthma, rheumatism, sprains, lumbago, catarrh, bronchitis, swollen joints, sciatica, and bursitis; that the articles would be efficacious in the cure, mitigation, and treatment of pulmonary tuberculosis and microbic diseases of the lungs and bronchial tubes, affections of the nose, rhinitis, tonsillitis, laryngitis, lobar pneumonia, broncho-pneumonia, empyema, otitis media, mastoiditis, adenoids, pharyngitis, adenitis, pleurisy and myositis (inflammation of the muscles); and that the articles would be efficacious to prevent malarial fever. The articles would not be efficacious for such purposes.

DISPOSITION: December 16, 1949. A plea of guilty having been entered, the court imposed a fine of \$300.

2967. Misbranding of Ko-rekT (dental device). U. S. v. Demetrie C. Siampaus (Siampaus Mfg. Co.) Plea of nolo contendere. Fine, \$100. (F. D. C. No. 26736. Sample No. 21860-K.)

INFORMATION FILED: September 28, 1949, District of Nebraska, against Demetrie C. Siampaus, trading as the Siampaus Mfg. Co., Omaha, Nebr.

ALLEGED SHIPMENT: On or about October 13, 1948, from the State of Nebraska into the State of Missouri.

PRODUCT: Examination showed that the *Ko-rekT* (dental device) consisted essentially of two counter-rotating rubber discs mounted on metal shafts, turned by a hand crank for the purpose of cleaning the teeth and massaging the gums.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in accompanying leaflets headed "Throw Away Your Tooth Brush," "Turn on that Smile with Ko-RekT," and "Startling New Discovery," were false and misleading. The statements represented and suggested that the device would prevent and heal gum infections, prevent tooth decay, heal pyorrhea, keep the gums and mouth healthy, eliminate tartar formation, force blood circulation to every part of the gum tissues, and stop bacteria at the gum line. The device would not fulfill the promises of benefits stated and implied.

DISPOSITION: December 15, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$100.

2968. Misbranding of Healthomatic devices. U. S. v. 6 Devices, etc. (F. D. C. No. 28235. Sample No. 52061-K.)

LIBEL FILED: October 21, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: During March and July 1949, by the Goodhealth Associates, from Bala-Cynwyd, Pa.

PRODUCT: 6 *Healthomatic devices* at Cleveland, Ohio, together with a number of booklets entitled "The Road To Health." The device was similar in construction to a wheelless bicycle. The pedals and handle bars could be moved by the operator or activated by an electric motor.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the device were false and misleading since the device was not effective for the purposes stated and implied: (on device) "Healthomatic Physical Activity Protects Health Perfection of Body Peace of Mind" and

(in booklet entitled "The Road to Health") "The Road To Health Healthomatic Physical Activity Protects Health Perfection of Body Peace of Mind * * * improves your health and renews your vigor. You will enjoy that refreshing flush of blood circulation that only a well conditioned body can know. Consider Healthomatic as a valuable aid to combat all those physical troubles from which you may suffer because you are physically inactive—over-weight, constipation, indigestion, backache, fatigue, poor circulation, nervous tension, headache, etc. * * * more than just a body conditioning instrument. * * * 1-Head—Acts as a Beauty Aid by stimulating the flow of blood through the Capillaries and helping keep the entire body in good health—Tends to relieve mental fatigue * * * Aids in correcting certain causes of headaches. 2-Neck—Helps contour the neck lines—Aids in the relief of nervous tension—Encourages relaxation and restful sleep. 3-Back—Tends to strengthen a weak back, improve posture and give more youthful lines. 4-Chest—Ventilates the Lungs more thoroughly—Aids in firming the Breasts and reducing underarm flabbiness. 5-Upper Abdominal Cavity—Aids in tightening up a sagging Stomach—Tends to activate Liver and Gall-Bladder, reduce indigestion and gas formation. 6-Waistline Area—Helps reduce waistline measurements, strengthen abdominal muscles and provide definite figure control. 7-Bowels—Combats constipation and promotes regularity of waste elimination. 8-Hips—Helps reduce bulging Hips, decrease buttocks and trim thighs. 9-Legs—Tends to shape legs to slender proportions, strengthen foot muscles and stimulate Blood circulation in cold Feet. * * * 12-Above All—It helps to stimulate the Blood Stream in its entirety, bring a fresh supply of energy to all parts of the Body, bring rest and relaxation to the Mind and Nerves."

DISPOSITION: January 10, 1950. The Healthomatic Corp., Bala-Cynwyd, Pa., claimant, having consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the booklets be destroyed and that the devices be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE*

2969. Misbranding of *Speedway Cough and Distemper Remedy*, *Speedway Absorbent Liniment*, *Speedway Condition Powder*, *Speedway Hoof Tonic*, and *Black Perfection Salve*. U. S. v. August W. Frueh (Energy Drug Co.). Plea of guilty. Fine, \$250. (F. D. C. No. 26739. Sample Nos. 30648-K to 30652-K, incl.)

INFORMATION FILED: October 13, 1949, Northern District of Ohio, against August W. Frueh, trading as the Energy Drug Co., Cleveland, Ohio.

ALLEGED SHIPMENT: From the State of Ohio into the State of California. Four of the five shipments were made in or about the month of May 1948, and the fifth shipment was made between the approximate dates of August 31 and September 18, 1948.

PRODUCT: Analysis disclosed that the *Speedway Cough and Distemper Remedy* consisted of a black syrupy liquid with an aromatic odor, and containing ammonium compounds and a trace of alkaloids, including strychnine; that the *Speedway Absorbent Liniment* consisted of a denatured alcohol containing benzoin and aromatics; that the *Speedway Condition Powder* consisted of a tan

*See also No. 2965.

powder consisting mainly of iron sulfate, organic matter, fenugreek, a small amount of santonin, and a trace of alkaloids; that the *Speedway Hoof Tonic* consisted of a yellow mineral oil, with an odor resembling that of crude oil; and that the *Black Perfection Salve* consisted of a black salve, with sulfur, charcoal, tannic acid, and a small amount of lead compounds.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles, which included an accompanying circular entitled "Speedway Veterinary Remedies," were false and misleading since the articles would not be efficacious for the purposes represented and suggested. These statements represented and suggested:

That the *Speedway Cough and Distemper Remedy* when administered to horses, would be efficacious in the treatment of cough and distemper; that it would relieve fever and restore normal temperature; that it would be efficacious in the treatment of shipping fever, colds, lung fever, "episodic acclimation," common pneumonia, and complicated pneumonia; and that it would be efficacious as a remedy for kidney troubles, and as a diuretic, stomachic, and stimulant;

That the *Speedway Absorbent Liniment* when administered to horses, would be efficacious for all lameness, bad back, bad legs, bowed tendons, and big knees; that it would be efficacious for restoring natural respiration between heats; that it would be efficacious for bad ankles, weak joints, and bad loins; and that it would be efficacious for strengthening weak muscles and for toning up muscles;

That the *Speedway Condition Powder* when administered to horses and colts, would be efficacious to stimulate the appetite of poor feeders, to increase the utilization of feed, to restore vital essentials, to tone the circulation, to benefit the entire nervous system, to increase the flow of gastric juices, and to tone the entire system; and that it would be efficacious as a tonic, tissue builder, blood purifier, worm expeller, general body builder, and conditioner;

That the *Speedway Hoof Tonic* would be efficacious in the treatment of contracted feet, thrush, and bad feet in horses; that it would grow new hoofs on horses; and that it would be efficacious to put horses' feet in a healthy condition;

That the *Black Perfection Salve* would be efficacious in the treatment of "hobble chafes," cracked heels, wounds and sores, saddle galls, severe chafing, and accompanying soreness in horses; and that it would be efficacious for growing a soft pliable, yet tough, skin on horses.

DISPOSITION: December 2, 1949. A plea of guilty having been entered, the court imposed a fine of \$250.

2970. Misbranding of Rex Wheat Germ Oil. U. S. v. VioBin Corp. Plea of nolo contendere. Fine, \$1,000. (F. D. C. No. 25608. Sample Nos. 83115-H, 15069-K, 24748-K.)

INFORMATION FILED: April 11, 1949, Eastern District of Illinois, against the VioBin Corp., Monticello, Ill.

ALLEGED SHIPMENT: On or about February 26, 1947, and May 10, 1948, from the State of Illinois into the States of Ohio, Wisconsin, and Michigan.

LABEL, IN PART: "Rex Wheat Germ Oil A cold processed, biologically tested, stable wheat germ oil."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, which included accompanying circulars entitled "The

Record of *Rex* Wheat Germ Oil," "Record Wheat Germ Oil," "Rex Wheat Germ Oil," and "Bulletin No. 6 Breeding and Maintenance of Dogs," and a letter addressed to "Dear Friend," were false and misleading. The statements represented and suggested that the article would be effective as an aid in the cure, mitigation, treatment, and prevention of breeding difficulties in cattle, swine, horses, sheep, rabbits, dogs, fox, and mink; that the article would be effective in the treatment and prevention of sterility in livestock; that it would be effective as an aid in the prevention of abortion in livestock; that it would be effective as an aid in the treatment and prevention of Bang's disease in livestock; and that it would be effective in the cure, mitigation, treatment, and prevention of skin diseases in dogs. The article would not be effective for the purposes represented.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: November 17, 1949. A plea of *nolo contendere* having been entered, the court imposed a fine of \$1,000.

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¹ (2961) Injunction contested. Contains findings of fact, discussion, and conclusion of law.

² (2963) Seizure contested. Contains opinion of the court.

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¹ (2961) Injunction contested. Contains findings of fact, discussion, and conclusion of law.

² (2963) Seizure contested. Contains opinion of the court.

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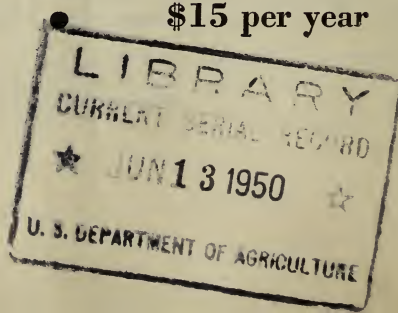
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FEDERAL SECURITY AGENCY**FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2971-2990

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

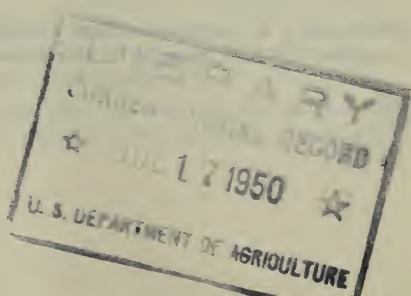
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DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE
DIRECTIONS OR WARNING STATEMENTS

2971. Misbranding of sulfathiazole lozenges and Hexital tablets. U. S. v. Joe Gailey (McGreevy Drug Co., No. 1). Plea of guilty. Fine, \$50. (F. D. C. No. 26713. Sample Nos. 27032-K, 27042-K.)

INFORMATION FILED: June 29, 1949, Western District of Missouri, against Joe Gailey, a partner in the partnership of McGreevy Drug Co., No. 1, Springfield, Mo.

INTERSTATE SHIPMENT: On or about January 30, 1948, from Indianapolis, Ind., of a quantity of *sulfathiazole lozenges*, and between the approximate dates of January 16, 1947, and September 20, 1948, from Raritan, N. J., of a quantity of *Hexital tablets*.

LABEL, WHEN SHIPPED: (Sulfathiazole lozenges) "Lozenges Sulfathiazole * * * 5 grs."; (Hexital tablets) "Each Tablet Contains Phenobarbital 20 Mg. * * * Hexestrol—3 Mg. Hexital." (Both products) "Caution: To Be Dispensed Only By Or On the Prescription of a Physician."

ALLEGED VIOLATION: On or about August 13 and September 20, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of *sulfathiazole lozenges* and *Hexital tablets* to be removed from the bottles in which they had been shipped, to be repacked, and to be sold to an individual without a prescription, which acts of the defendant resulted in the lozenges and tablets being misbranded. The repackaged drugs were labeled "Sulfathiazole Lozenges McGreevy Drug Co. * * * Springfield, Mo." and "Hexital McGreevy No. 1, Springfield, Mo."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the label borne on the containers of the repackaged drugs contained no statement of the quantity of the contents; Section 502 (f) (1), the containers of the repackaged drugs bore no labeling containing directions for use; and, Section 502 (e) (2), the repackaged *Hexital tablets* were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and the label borne on the repackaged tablets failed to bear the common or usual name of each active ingredient, namely, "phenobarbital" and "hexestrol."

Further misbranding, Section 502 (d), the repackaged *Hexital tablets* were a drug for use by man and contained a chemical derivative of barbituric acid, namely, "phenobarbital," which derivative had been by the Administrator of the Federal Security Agency, after investigation, found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (2), the repackaged *sulfathiazole lozenges* bore no labeling containing warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: November 18, 1949. A plea of guilty having been entered, the court imposed a fine of \$50.

2972. Misbranding of seconal sodium capsules and amphetamine phosphate tablets. U. S. v. George R. Murchison (Murchison's Pharmacy). Plea

of guilty. Fine, \$200. (F. D. C. No. 26711. Sample Nos. 22382-K, 22820-K, 23146-K to 23148-K, incl.)

INFORMATION FILED: July 25, 1949, Northern District of Texas, against George R. Murchison, trading as Murchison's Pharmacy, Fort Worth, Tex.

INTERSTATE SHIPMENT: From the States of Indiana and Iowa, of quantities of *seconal sodium capsules* and *amphetamine phosphate tablets*.

LABEL, WHEN SHIPPED: (Portion) "Amphetamine Phosphate 10 Mg. [or "Seconal Sodium 1½ grs.]" * * * Caution: To be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about March 15 and 22 and October 16 and 18, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of the capsules and tablets to be repacked and sold to various persons without a prescription, which acts of the defendant resulted in the capsules and tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs bore no labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), they bore no label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *seconal sodium capsules* contained a chemical derivative of barbituric acid, which derivative had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the repackaged *seconal sodium capsules* failed to bear a label containing the name and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged drugs were not designated solely by names recognized in an official compendium, and, with the exception of one sale of *seconal sodium capsules*, they failed to bear labels bearing their common or usual names, "seconal sodium" and "amphetamine phosphate"; Section 502 (f) (1), the repackaged drugs failed to bear labeling containing directions for use; and, Section 502 (f) (2), the repackaged *amphetamine phosphate tablets* bore no labeling containing warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: October 17, 1949. A plea of guilty having been entered, the court imposed a fine of \$200.

2973. Adulteration and misbranding of Radiodine Ampuls and misbranding of Iriodine Ampuls, Tropiodin Colloidal Iodine, and Chloro-Iodine Colloidal Concentrate. U. S. v. Albert B. Trencavel and William C. McGregor (Trencavel Co.). Plea of guilty on behalf of William C. McGregor; fine, \$200 and costs. Case pending against defendant Trencavel. (F. D. C. No. 24234. Sample Nos. 1550-H, 1551-H, 38898-H, 38899-H.)

INFORMATION FILED: On or about September 27, 1948, Northern District of Illinois, against Albert B. Trencavel and William C. McGregor, trustees of the Trencavel Co., a common-law trust, Chicago, Ill.

ALLEGED SHIPMENT: On or about July 2 and October 31, 1946, from the State of Illinois into the States of Florida and Wisconsin.

PRODUCT: Examination disclosed that the *Tropiodin Colloidal Iodine* (veterinary product) was a deep-blue fluid consisting chiefly of water, starch, iodine, and

potassium iodide; that the *Chloro-Iodine Colloidal Concentrate* (veterinary product) was a syrupy, red-orange fluid consisting chiefly of glycerin, iodine, potassium iodide, potassium and sodium chlorides, and water; that the *Radiodine Ampuls* consisted essentially of iodine (0.002 gram per cc.), sodium iodide, and water, and was contaminated with undissolved material; and that the *Iriodine Ampuls* consisted essentially of iodine (0.006 gram per cc.), sodium iodide, starch, and water.

NATURE OF CHARGE: *Radiodine Ampuls.* Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it purported and was represented to be of a purity and quality suitable and appropriate for intravenous and intramuscular injection, whereas it was not of a purity and quality suitable and appropriate for intravenous and intramuscular injection since it contained undissolved material.

Radiodine Ampuls and Iriodine Ampuls. Misbranding, Section 502 (b) (1), the boxes and ampuls containing the articles bore no labels containing the name and place of business of the manufacturer, packer, and distributor; Section 502 (b) (2), the ampuls containing the articles bore no labels containing a statement of the quantity of the contents; Section 502 (e) (2), the articles were not designated solely by a name recognized in an official compendium and were fabricated from two or more ingredients, and their labels failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (1), the labeling of the articles bore no directions for use.

Tropiodin Colloidal Iodine. Misbranding, Section 502 (a), certain statements in the labeling of the article which labeling included a number of accompanying booklets entitled "Tropiodin" and blotters headed "Directions For Use of Tropiodin," were false and misleading. The statements represented and suggested that when used as directed, the article would be efficacious in the treatment of inflammatory processes, infections in general, mastitis, pneumonia, white scours, contagious abortion, sterility, and Johne's disease; that the article would be effective for off-feed conditions in animals; that it would be an effective antiseptic and bactericide for intravenous, intramuscular, and subcutaneous injections, and for the mucous membrane in general; that when used as directed, it would be effective in destroying disease-producing germs; that it would be effective in combating inflammation and in detoxifying tissues and body fluids; that it would promote toxin removal by deeply stimulating the lymphatic system; that it would be effective in reducing fever and would interfere with the progress of disease; that it would be effective as a therapeutic agent of great curative powers; that it would be efficacious in the treatment of infections in general, and diseases due to improper nutrition, feed conditions, or inflammation; that when used as directed, the article would be efficacious in the treatment of acute and chronic mastitis in cows and goats; that it would be efficacious in the treatment of pneumonia in cows and bulls, shipping fever, milk fever, white scours, sterility, toxic infections, and inflammatory and bacterial conditions; that when used as directed, the article would be efficacious in the treatment of endometritis, cervicitis, vaginitis, *Brucella abortus*, *Trichomonas* and *corynebacteria* infection, cystic degeneration of the ovaries, and pyometra; that it would be efficacious in the treatment of the various causes of abortion and sterility; that it would be efficacious in the treatment and eradication of trichomoniasis in cattle; and that it would be efficacious in the treatment of wooden tongue and timber tongue in cases of actinomycosis. The article would not fulfill the promises of benefit suggested and implied.

Chloro-Iodine Colloidal Concentrate. Misbranding, Section 502 (a), certain statements in the labeling of the article, which labeling included a number of accompanying booklets entitled "Chloro-Iodine," were false and misleading. The statements represented and suggested that the article would be effective as an internal and external remedy for better animal health; that when used as directed, the article would be efficacious in the treatment of infections associated with staphylococci, streptococci, *corynebacteria*, abortion bacilli, trichomonads, nematodes, cestodes, trematodes, and other equally virulent and destructive organisms; that when used as directed, the article would be effective as an antiseptic, germicide, and vermicide; that it would be effective as a curative agent in specific diseases; that it would increase and enhance the natural powers of producing dairy food and would ward off ailments which disastrously ravage animal flesh; that it would be effective in preventing and combating disease in livestock, in preventing contamination and blood poison setting in, and in warding off infection caused by disease germs attacking the body; that it would be effective as a sterilizing agent; that it would inhibit sepsis; that when used as directed, the article would be inimical to all pathogenic organisms that infect the animal body; that the article was a healing agent; that when used as directed, it would be effective in the treatment of mastitis, contagious abortion, sterility, and Johne's disease (paratuberculosis); that it would be effective in the eradication of disease; that it would maintain resistance to disease; that it possessed curative properties; that it would be effective as a prophylactic and healer, and as a disinfectant for inflammatory conditions, abscesses, carbuncles, skin infections of all kinds, and the mucous membrane in general; that it would be effective against all infections of the eye, and of the entire genital tract; that it would be effective as a dewormer for goats, sheep, and hogs, and as a bactericide in dysentery of animals; that it would be effective in entirely deworming animals; that it was specific in destroying the causative germs of dysentery, in eradicating the irritation and inflammation of the intestines, and in stopping diarrhea; that the article was a curative and prophylactic for warding off mastitis, milk fever, dysentery, off-feed conditions, diseases that originate from improper feeding, and bacterial and parasitic invasion; that it would be effective in controlling sterility in cows; and that it would be efficacious in the treatment of wooden tongue, timber tongue, endometritis, cervicitis, and vaginitis following *Brucella abortus* (Bang's disease), and *Trichomonas* and *Corynebacteria* infection. The article would not fulfill the promises of benefit suggested and implied.

DISPOSITION: January 17, 1949. A plea of guilty having been entered on behalf of William C. McGregor, the court imposed a fine of \$200 and costs against this defendant. Inasmuch as service of process could not be obtained on Albert B. Trencavel because of his absence from this country, no action was taken in his case and it has remained pending.

2974. Misbranding of Philcapco Testans. U. S. v. 1 Bottle * * *. (F. D. C. No. 27998. Sample No. 51850-K.)

LABEL FILED: September 23, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: On or about June 1, 1949, by Philadelphia Capsule Co., Inc., from Philadelphia, Pa.

PRODUCT: 1 440-capsule bottle of *Philcapco Testans* at Mansfield, Ohio.

LABEL, IN PART: (Bottle) "Philcapco Testans * * * Each capsule approximates 2 drachms of Fresh Testicular Beef Substance. This preparation

does not contain any known therapeutically useful constituent of the gland.
Caution: To be used only by or on the prescription of a physician."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since its labeling failed to bear any directions for use. (The article, although bearing the prescription legend, was not entitled to the exemption under the regulations from the requirement that its labeling bear adequate directions for use since adequate information for the use of the article was not readily available to physicians, because the article was inert and, therefore, adequate information for its use as a drug did not exist.)

DISPOSITION: November 7, 1949. Default decree of condemnation and destruction.

2975. Misbranding of Black Eagle Brand Medicine and Millerhaus' Famous Liniment. U. S. v. 140 Bottles, etc. (F. D. C. No. 28004. Sample Nos. 13817-K, 13818-K.)

LABEL FILED: September 26, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 16, 1949, from Cincinnati, Ohio.

PRODUCT: 140 8-ounce bottles of *Black Eagle Brand Medicine* and 120 1-ounce bottles of *Millerhaus' Famous Liniment* at Philadelphia, Pa., in the possession of Willie Palmer.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use for the purposes for which they were intended. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 28, 1949. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

2976. Adulteration and misbranding of amphetamine HCL tablets. U. S. v. 9 Bottles * * *. (F. D. C. No. 27624. Sample No. 46720-K.)

LABEL FILED: August 4, 1949, Northern District of West Virginia.

ALLEGED SHIPMENT: On or about May 7, 1949, by the Uno Laboratories, from Pitman, N. J.

PRODUCT: 9 bottles of *amphetamine HCL tablets* at Wheeling, W. Va. Examination showed that each tablet contained 9.64 milligrams of racemic desoxyephedrine hydrochloride but no amphetamine hydrochloride.

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), tablets containing 9.64 milligrams of racemic desoxyephedrine hydrochloride each but no amphetamine hydrochloride had been substituted in whole or in part for "amphetamine hydrochloride tablets," which the article purported to be.

Misbranding, Section 502 (a), the label statement "10,000 * * * Amphetamine HCL Tablets 10 Mgm. per Tablet" was false and misleading as applied to an article containing no amphetamine hydrochloride.

DISPOSITION: October 28, 1949. Default decree of condemnation and destruction.

*See also No. 2973.

2977. Adulteration of chorionic gonadotropin. U. S. v. 47 Vials * * *.
(F. D. C. No. 27721. Sample No. 52057-K.)

LIBEL FILED: August 25, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: On or about December 30, 1948, and January 5, 1949, from New York, N. Y.

PRODUCT: 47 10-cc. vials of *chorionic gonadotropin* at Canton, Ohio. Examination showed that the product consisted of *chorionic gonadotropin*, with a potency of not more than 1,250 International Units per vial. The product was invoiced as one having a potency of 5,000 International Units per vial.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 5,000 International Units of chorionic gonadotropin per vial. The product was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: November 2, 1949. Default decree of condemnation and destruction.

2978. Adulteration of procaine injection. U. S. v. 44 Vials * * *. (F. D. C. No. 28259. Sample No. 57344-K.)

LIBEL FILED: November 2, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about August 15, 1949, from New York, N. Y.

PRODUCT: 44 vials of *procaine injection* at Irvington, N. J.

LABEL, IN PART: (Vial) "No. 97F 100 cc. Vial Multiple Dose Procaine Injection 1%."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Ampuls of Procaine Hydrochloride," a drug the name of which is recognized in the National Formulary, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 19, 1949. Default decree of condemnation and destruction.

2979. Adulteration of Thiosol and calcium gluconate. U. S. v. 16 Vials, etc. (F. D. C. No. 28025. Sample Nos. 58213-K, 58215-K.)

LIBEL FILED: October 5, 1949, Southern District of California.

ALLEGED SHIPMENT: On or about July 5 and 26, 1949, by Vincent Christina & Co., Inc., from New York, N. Y.

PRODUCT: 16 100-cc. vials of *Thiosol*, and 4 boxes, each containing 24 10-cc. ampuls, of *calcium gluconate*, at Los Angeles, Calif.

LABEL, IN PART: "Thiosol An organic solution of Sulfur Intramuscular—Intravenous" and "Calconate 10% Solution Each 10 cc contains 1 Gm. Calcium Gluconate U. S. P. * * * For Intravenous or Intramuscular Use."

NATURE OF CHARGE: Adulteration, Section 501 (b), the *calcium gluconate* purported to be, and was represented as, "Calcium Gluconate Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material; and, Section 501 (c), the purity and quality of the *Thiosol* fell below that which it purported and

was represented to possess since it was for parenteral administration and was contaminated with undissolved material.

DISPOSITION: November 8, 1949. Default decree of condemnation and destruction.

2980. Adulteration of vitamin B₁. U. S. v. 50 Vials * * *. (F. D. C. No. 28260. Sample No. 57360-K.)

LIBEL FILED: November 2, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about April 14, 1949, from New York, N. Y.

PRODUCT: 50 vials of *vitamin B₁* at Union City, N. J.

LABEL, IN PART: (Vial) "30 cc. Multiple Dose Vial Vitamin B₁ (Thiamine Hydrochloride) * * * injected intravenously or * * * intramuscularly."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be, and was represented as, "Thiamine Hydrochloride Injection," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 19, 1949. Default decree of condemnation and destruction.

2981. Adulteration and misbranding of Elixir Theratone "B." U. S. v. 6½ Cartons, etc. (F. D. C. No. 27795. Sample No. 56216-K.)

LIBEL FILED: September 2, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about January 20, 1949, by the Academy Mfg. Drug Corp., from New York, N. Y.

PRODUCT: *Elixir Theratone "B."* 6½ cartons, each containing 4 1-gallon bottles, 65 1-pint bottles, and 150 1-ounce bottles. The pint and ounce bottles had been repacked from gallon-size bottles by the consignee and labeled essentially the same as the gallon bottles.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Each Teaspoonful (4 cc.) contains: * * * Niacinamide 10.0 mg.," since the article contained less than the declared amount of niacinamide.

Misbranding, Section 502 (a), the label statement "Each Teaspoonful (4 cc.) contains: * * * Niacinamide 10.0 mg." was false and misleading as applied to the article, which contained less than 10.0 mg. of niacinamide.

DISPOSITION: November 2, 1949. Default decree of condemnation and destruction.

2982. Adulteration and misbranding of surgical dressings. U. S. v. 25 packages * * *. (F. D. C. No. 28342. Sample No. 30230-K.)

LIBEL FILED: November 16, 1949, Southern District of California.

ALLEGED SHIPMENT: On or about September 12, 1949, by Surgical Dressings, Inc., from Boston, Mass.

PRODUCT: 25 packages of *surgical dressing* at Los Angeles, Calif. Examination showed that the product was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: "Size 2'' x '' * * * Sterilastic Dressing Bandage."

NATURE OF CHARGE: Adulteration, Section 501(c), the purity and quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Sterilastic First Aid Bandage * * * Surgical Dressing * * * The gauze supplied with Sterilastic may be used in an emergency" were false and misleading as applied to the article, which was not sterile.

DISPOSITION: December 28, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

2983. Misbranding of Sulphocol capsules. U. S. v. 251 Bottles * * *. (F. D. C. No. 27754. Sample No. 61249-K.)

LIBEL FILED: September 19, 1949, Eastern District of Missouri; Amended libel filed on or about September 27, 1949.

ALLEGED SHIPMENT: On or about June 10 and July 8, 1949, by the National Drug Co., from Philadelphia, Pa.

PRODUCT: 251 100-capsule bottles of *Sulphocol capsules* at St. Louis, Mo. Examination showed that the product consisted of capsules containing a brownish-white powder consisting in part of sulfur.

LABEL, IN PART: "Capsules Sulphocol 5 grains (0.3 Gm.) Colloidal Sulfur Compound."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "For use where sulfur therapy is indicated as in chronic arthritis and allied conditions" was false and misleading since the article was not of benefit in these conditions.

DISPOSITION: November 10, 1949. Default decree of condemnation and destruction.

2984. Misbranding of Slim-O. U. S. v. 197 Bottles, etc. (F. D. C. No. 28020. Sample No. 51355-K.)

LIBEL FILED: October 4, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: On or about September 7, 1949, by Beauty Sales, from Hollywood, Calif.

PRODUCT: 197 7-ounce bottles of *Slim-O* at Cincinnati, Ohio, together with a number of leaflets entitled "Beauty Sales" and a newspaper mat entitled "Lose Excess Fat With Slim-O" at Cincinnati, Ohio.

Examination disclosed that the product consisted of sodium sulfate, sodium carbonate, and citric acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and similar statements in the circular and newspaper mat were false and misleading since the product would not be effective for the purposes stated and implied: "Slim-O [Picture of a slender female] Easiest, Safest Way to a Beautiful, Glamorous, Trimline Figure A More Lovely Figure The Easy Slim-O Way * * * Slim-O will help you take off inches of excess fat in the right spots, leaving the skin firm * * * No more worry about

*See also Nos. 2973, 2976, 2981, 2982.

sagging tissues and wrinkles * * * Slim-O is the newest, easiest way to lose excess fat and maintain a beautiful figure—always."

DISPOSITION: November 9, 1949. Default decree of condemnation and destruction.

2985. Misbranding of mineral oil. U. S. v. 108 Bottles * * *. (F. D. C. No. 27682. Sample No. 55206-K.)

LABEL FILED: On or about August 9, 1949, District of Kansas.

ALLEGED SHIPMENT: On or about November 5, 1948, by Rozelle, Inc., from St. Louis, Mo.

PRODUCT: 108 1-pint bottles of *mineral oil* at Hutchinson, Kans.

LABEL, IN PART: "Imperial Brand Mineral Oil."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "A satisfactory internal lubricant for * * * nursing or expectant mothers" was false and misleading since the article was not a safe drug for use by nursing or expectant mothers.

DISPOSITION: September 30, 1949. Default decree of condemnation and destruction.

2986. Misbranding of Doctor's Prescription Rx 7-11. U. S. v. 136 Bottles, etc. (F. D. C. No. 27461. Sample Nos. 55260-K, 55549-K.)

LABEL FILED: On on about July 20, 1949, Western District of Missouri.

ALLEGED SHIPMENT: On or about June 6, 1949, by the Murrell Laboratories, from Norman, Okla.

PRODUCT: 136 bottles of *Doctor's Prescription Rx 7-11* at Kansas City, Mo., together with a number of leaflets entitled "say goodbye to all scalp disorders." Examination showed that the product consisted essentially of water, alcohol, and glycerin, and small proportions of sulfanilamide and sulfathiazole, and red coloring matter.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the leaflets were false and misleading since the article was not effective in the treatment of the conditions stated and implied: "say goodbye to all scalp disorders * * * a scalp treatment * * * Relieves your scalp of * * * Dermatitis and Seborrheic * * * rid your scalp of Scales."

DISPOSITION: December 6, 1949. Default decree of destruction.

2987. Misbranding of Radiant Ozone Generators. U. S. v. 1 Device * * * (and 6 other seizure actions). Tried to the court and jury. Verdict for the Government. Decree of condemnation. (F. D. C. Nos. 25779, 27358 to 27362, incl., 27829. Sample Nos. 21777-K, 29277-K to 29280-K, incl., 29780-K, 49801-K, 49802-K.)

LABELS FILED: September 29, 1948, and July 18 and September 12, 1949, District of Colorado and Western District of Oklahoma.

ALLEGED SHIPMENT: Between the approximate dates of May 25, 1948, and April 23, 1949, by J. C. Gage and the Ozone Clinic, from Kansas City, Mo.

PRODUCT: 12 *Radiant Ozone Generators* at Oklahoma City, Okla., and Lamar and Denver, Colo., together with a number of leaflets and circulars entitled "The Radiant Ozone Generator," "A Few Suggestions," and "How to Use the Radiant Ozone Generator For the Best Results at Home," and a number of pages of testimonials. Examination showed that the device consisted of a

wooden cabinet, with neon-type tubes on top which were connected with a transformer in the cabinet. When plugged into an ordinary household electric current, the primary leads of the transformer activated the gas in the tubes, one type of which gave off a blue, and the other a red, hue. When the device was in operation, it produced ozone.

NATURE OF CHARGE: Misbranding, Section 502 (a) certain statements in the accompanying leaflets and testimonials were false and misleading since the device was not effective in the treatment of the symptoms, conditions, or diseases stated, nor for the purposes mentioned. The statements represented and suggested that the device would produce ozone, rays, color, and vibration, which were claimed to be the four essential things for health and would thereby relieve suffering from different incurable diseases; that the device would destroy all germs and bacteria, deodorize and purify the air, purify the blood, and rejuvenate the entire body; that it would be effective in the treatment of arthritis, asthma, anemia, cancer, diabetes, sinus affections, pneumonia, rheumatism, piles, varicose veins, neuritis, colds, tonsillitis, sore throat, headache, stomach ache, earache, toothache, indigestion, fever, and la grippe; that it would ozonize the body and assist one in getting the best results for various diseases; that it would revitalize the body; that it would be effective in the treatment of angina, diphtheria, mumps, whooping cough, bladder and kidney troubles, blood disorders, eye trouble, catarrh, heart trouble, hay fever, sinus trouble, liver trouble, prostate gland trouble, colitis, constipation, pneumonia fever, paralysis, ulcers, sores, sprains, varicose veins, tuberculosis, and mastoid ear; that it would be effective in the treatment of throat troubles, chicken pox, serious colds, cancer of the breast, inflammation of the kidneys, neuritis, neuralgia, disease caused by impure blood, ailments caused by poor circulation, stomach trouble, enlarged heart, cataract, bronchial asthma, appendicitis, chronic constipation, weakened run-down condition, sciatic rheumatism, and partial paralysis; and that it would be effective in aborting pneumonia and flu, maintaining and restoring health and strength, cleansing the blood, scattering blood clots, and killing germs that are in the blood.

DISPOSITION: J. C. Gage appeared as claimant for the device, which was seized at Oklahoma City. Pursuant to a stipulation between the claimant and the United States Attorney for the Western District of Oklahoma, the libel action in that district was transferred to the District of Kansas on November 22, 1948. On December 13, 1948, the action was transferred from the District of Kansas to the Western District of Missouri pursuant to a stipulation between the Government and the claimant. Thereafter, the claimant filed a motion to dismiss the libel proceedings, and on January 10, 1949, such motion was overruled. An answer then was filed by the claimant, denying that the device was misbranded. Thereafter, the Colorado libel actions, upon application by the claimant and with the consent of the Government, were ordered transferred to the Western District of Missouri and consolidated for trial with the action then pending in that district. The matter came on for trial before the court and jury on November 14, 1949, and at the conclusion of the testimony on November 18, 1949, the court gave the following charge to the jury:

DUNCAN, *District Judge*: "Ladies and gentlemen of the jury, you have now heard all of the testimony in this case and the arguments of counsel, and it now becomes the duty of the Court to charge you as to the law. I am not sure whether all of the members of this panel have been on juries in this court, or some other division of the court, since you have been serving on it. Some of you have been on juries in this court I know and some of the things

the Court may say to you will be repetition, if you have served before, but it is the duty of the Court in every case to charge the jury as to the law.

"Now, in the United States courts the Court has the duty of charging the jury as to the law and the Court also has a right to advise the jury as to the facts. That is not true in our state courts. So that we may not confuse our practice, in the state courts the court's instructions are written instructions which may be taken to the jury room by the jury. They are made before the arguments of counsel and the court cannot comment, as we say, upon the evidence, but in the federal court the instructions of the court are oral, although in cases where the law may be complicated, the Court's instructions may be written, but for all practical purposes they are oral and you cannot take those instructions in any written form to your jury room. It is, therefore, essential that you pay as close attention as you can to the Court's charge because in your deliberations upon the case it will be necessary for you to remember and carry with you in your mind the law as to the case.

"I think the law in this case is not complicated. Under our form of practice in this country where we have the jury system, the sole responsibility of determining what the facts are is for the jury. It is the Court's duty, as I said, to charge you as to the law. Now, you may not agree with what the law is as the Court gives it to you. The Court might even be mistaken as to what the law is, but as the Court gives you the law, it is as the Court believes it to have been construed and to have been written by the Congress, by the legislative branch of our government, and as it has been construed by the courts whose duty it is to construe the law. There are times when the judge who charges a jury as to the law may not in his own mind, in his own way of legal thinking, agree that the law ought to be as it is, but the Court does not write the law. Neither does the jury write the law. You and I must take it as it is given to us by the legislative branch of our government and by the courts who construe it. So, when you have determined what the facts are, you will apply the law to those facts, or the facts to the law. Those findings by you are binding upon this Court. They are binding upon this Court and any other court to which the case might go. If either party losing the case should be dissatisfied with the result of it, they have the right to an appeal and another court will pass upon it, but only on questions of law in determining whether or not the Court has erred in the admission of testimony or in its construction of the law and the charge to the jury. If there is any basis in fact or in law for the finding that you have made as to the facts, then it is binding upon this Court and any other court. So yours is the greater responsibility.

"Of course, we should approach this case, as every other case, without sympathy for anybody or prejudice against anybody. You and I in our duty under the oath that we have taken—I to uphold the Constitution and the laws of the United States, and you to try the issues joined as they come to you, determine the facts as they come to you from the witness stand—should not be actuated by any motives of prejudice, by any motives of sympathy. It should not make any difference to you and to me whether everybody in Kansas City or everybody in Missouri is interested in this case on one side or the other, in a determination of what those facts are. It makes no difference that the Government is on one side of this case and the device which is in evidence is on the other. We are not concerned about that and no person, regardless of who or where, has any right to question your verdict when you leave this courtroom, and if any person should question your verdict when you leave this courtroom, it would be your duty in the maintenance of the honor and dignity of the Court to report that fact back to the Court and that person would then be liable to be brought into court and charged with contempt of court. So, when you leave this courtroom no person any place has a right to question you or a right to question your motives in anything you may do. They may disagree with me as to the law that I give. They might disagree with you as to the findings of fact, but they have no right to bring you, or attempt to bring you to accountability for any finding that you may make.

"This is not the usual case. I don't mean the facts, but I mean the nature of the case. It is what we term a "libel" proceeding. It is an offshoot of the old admiralty law in which, if any ship commits a wrong, com-

mits damage, then the suit is brought not against the owner, but against the ship itself, whatever the name of the ship may be. So, this is an offshoot of that, what we call a "libel proceeding." This suit is not brought against Mr. Gage: it is brought against this machine, this device for the purpose, if the Government is successful, of taking possession of it and then the Court will determine what is to be done with it.

"It is an inanimate thing; it is against the *res*, the thing itself and after the initiatory proceedings have been made, then the owner, the claimant of the machine comes in and files a claim to take the machine back and that person is known as the claimant. That is Mr. Gage in this case. When it was taken from those who had it, under the authority of the Court, under a writ alleging certain things that have been alleged here, then Mr. Gage came into Court and filed a claim for it. So, he is now called the "claimant" and if your finding be for the claimant, then the machines will be turned back. If it isn't, then they will remain in the custody of the Government until they are otherwise disposed of.

"There isn't any question about the jurisdiction of this Court. The Government of the United States had a right, under the Pure Food and Drug Act, to do what it did. Now, we have a dual form of government. The states and the federal government are each sovereign within their own rights and within their own jurisdiction. The federal government has no authority except that which has been specifically delegated to it by the people and such authority as has not been delegated to it remains within the states under their own laws and under their own constitution. So the federal government obtains jurisdiction over matters of this kind purely because of the interstate features of it, that is, when an article in commerce is transferred from one state to another, it is moving in interstate commerce and under the Constitution the federal government has a right to legislate with respect to matters moving in commerce, but not with respect to matters that are wholly within the state. That jurisdiction and authority over them is vested in the state and in the legislature under the authorities of the states, so that in this case the only way the government gets jurisdiction is because these devices—and it is admitted, there is no dispute about that, the claimant admits it—these devices or machines were sold and shipped in interstate commerce and that the advertising and pamphlets about which the government complains moved with the machine or were a part of it. The advertising and pamphlets or letters, or whatever it may be, do not necessarily have to accompany the machine as it is moved from one state to another. If it is a part of the transaction, then under the law it comes within the definition of interstate commerce and accompanies the machine. The Supreme Court of the United States has passed upon that question. So there is no question of that kind involved in this case and there is no proceeding here directly against Mr. Gage.

"You are instructed that under the Federal Food, Drug and Cosmetic Act the shipment in interstate commerce of any device that is misbranded is subject to seizure and condemnation. You are not concerned yourselves with the interstate commerce question as the claimant has admitted he shipped all of the devices and labeling involved in this trial in interstate commerce.

"You are not concerned with any of the machines that belong to any persons. This is not a proceeding to prevent the making of this machine or to prevent the sale of it. This is a proceeding solely to determine whether or not the label, that is the things that have been read to you here, the advertising, the testimonials that have accompanied these machines, are false or misleading in any particular. Now, that is the sole and only question that you are concerned with here, and in that connection you are instructed that the Food, Drug and Cosmetic Act provides that a device shall be deemed to be misbranded if its labeling is false or misleading in any particular.

"The term 'device' is defined in the Federal Food, Drug and Cosmetic Act and as it applies to the issues in this case means 'instruments, apparatus and contrivances intended (1) for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man.' You are instructed that each of the devices referred to in the 7 libels filed herein is a device within the meaning of the Federal Food, Drug and Cosmetic Act.

"The Federal Food, Drug and Cosmetic Act defines 'labeling' to mean, 'All labels and other written, printed or graphic matter (1) upon any article or

any of its containers or wrappers, or (2) accompanying such article,' and I have explained to you that 'accompanying' does not necessarily mean that it is in the box or must be attached to it. It means that it is a part of it and travels to and gets from one state to another to the person who has purchased or acquired the machine, or been sent rather by the maker of the machine.

"You are instructed that Government's Exhibits 2 and 3 constitute 'labeling' in this case and apply in each of the 7 cases on trial.

"Now, I assume, gentlemen, that those exhibits will be made available for the jury to take to the jury room and I am going to rely upon that assumption, so I am not going to take the time to go over all of this evidence because you remember the evidence as well as I do.

"In that connection I think the Court should call your attention to the fact, and without comment, that as a part of the labeling it is stated that 'the Radiant Ozone Generator has been tried with great success on the following diseases: arthritis, asthma, anemia, cancer, diabetes, sinus, pneumonia, rheumatism, piles, varicose veins, neuritis and colds. According to good authority there are more people suffering from arthritis than from heart disease, cancer and tuberculosis. What causes this disease, we believe we have found the answer to that question. We also believe the future will have many surprises for us as far as the health giving qualities of Ozone are concerned. It is our firm conviction that the surface has not even been scratched yet in the application of the use of Ozone, color, rays and vibration in the treatment and destruction of microbic diseases in human beings. Ozone will some day change our present practice of medicine and surgery because of its powerful influence on bacteria. In cases where the patients were able to inhale at all, they were at once relieved and successfully carried over the crisis.'

"Referring to influenza, and there are many others that you will have before you in determining whether or not the labeling is false, you are instructed that as used in the Federal Food, Drug and Cosmetic Act, the word 'false' applies to 'any representation or suggestion which is inaccurate, incorrect, untrue or an erroneous statement of fact.' You are instructed that the word 'misleading,' as used in the Act, applies to 'any written, printed, or graphic matter which misleads or deceives or has a tendency to lead into error, to lead astray or to lead into the wrong path.' You are further instructed that deception may result from the use of statements not technically false or which may be literally true. The aim of the Act is as much to prevent deception which may result from indirection and ambiguity, as well as from statements or misrepresentations which are false.

"You are further instructed that it is not difficult to choose statements, representations, pictures, symbols or slogans which will not deceive and those which are ambiguous and liable to deceive should be read favorably to the accomplishment of the purpose of the Act, namely, the avoidance of fraud and deception upon the purchasing public. Statements that are ambiguous and liable to mislead, or which create or lead to false impressions in the mind of the reader, are misleading within the meaning of the law. In determining whether the labeling involved is false or misleading for any of the reasons claimed, you will consider whether the statements complained of are likely to create a false or misleading impression in the mind of any person who reads such statements pertaining to the claims made for the devices involved in this case.

"In determining whether any statement in the labeling, as previously explained to you, is false or misleading in any particular, and in determining whether any such statement represents or suggests that the article of device when used according to directions is effective in the cure, mitigation, treatment or prevention of any condition or disease, you are instructed that the words, 'statement' or 'graphic materials' used in such labeling should be given their ordinary meaning, that is, the meaning that would be attributed to them by the ordinary person to whom they are addressed. If you believe from the credible evidence that an ordinary person after reading any of the statements complained of in said labeling would ordinarily be led to believe that a particular condition or disease would be cured, mitigated or prevented by the recommended use of the machine, or that the machine when so used would be a competent treatment for such disease or condition, and if you further believe from the credible evidence that the machine when used as directed would

either not cure, mitigate, or prevent, or be a competent treatment for such condition or disease, then the device is misbranded and the shipments thereof in interstate commerce constitute violations of the Federal Food, Drug and Cosmetic Act.

"And may I pause here to say that the duty is upon the government to prove the case, that is, the misleading statements, by the preponderance or greater weight of the evidence. That does not necessarily mean the greater number of witnesses testifying, but such evidence as is more satisfying and convincing to the jury.

"The Government is not required to prove that the devices involved are dangerous to health or harmful in any way. The Government is only required to prove the presence of a false or misleading statement in the labeling.

"The label on the device in evidence indicates that the device is registered in the United States Patent Office. Now, this matter came up yesterday and the Court made a ruling on it. Neither this label nor the fact that there has been compliance with the laws involving patents, gives the claimant, J. C. Gage, the right to disseminate any false or misleading statement on the labels or in the labeling of these devices. In reaching your verdict you will completely disregard all reference to patents. That question has absolutely nothing to do with whether or not the machine does or does not do the things which are claimed for it, or which are charged to it.

"During the course of the trial references have been made to affidavits and testimonials; printed matter containing testimonials and matter in the nature of testimonials appear in some of the exhibits. I must give you a word of caution about them. In your deliberations they are not to be considered by you as proof of the effect of the use of this device in connection with the diseases or conditions mentioned therein. There was no evidence to show that the authors of the testimonials were qualified to diagnose diseases or conditions, nor that they were qualified to evaluate the results of the use of the Radiant Ozone Generator on certain types of those diseases. The Government has based allegations of misbranding on some of the testimonials that are in evidence and has properly introduced evidence for your consideration, to prove its allegations of false and misleading statements. The authors of the testimonials may have been deceived as to the nature of the diseases or conditions from which they suffered or as to the effect of the use of the device.

"I think I stated to the jury in the early part of this charge—if I did not do so I should and will now—that any comment which the Court may make upon any evidence in this case or any factual situation, it is not binding upon you. It is simply the opinion of the Court or the judge of the court, because you are the sole judges of the credibility of the witnesses and the value you will give to their testimony. It is just the opinion of the Court and is not to be considered by you in any factual matter as you would be required to follow the suggestions of the charge of the Court as to the law.

"Now, in this case many objections were made and sustained by the Court as to the labeling of certain diseases by the witnesses. It is the law that laymen who are not trained in medicine, diagnosis, cannot say that they have heart trouble or stomach trouble or say that they have cancer or something of that sort. Those are matters that are left to those who are trained in the science to determine. One may think he has a heart disorder. It may result from overeating or from gastritis or some other ailment of the human body. One may think they have a cancer and yet when it is analyzed microscopically it may be determined it is not cancer, and it is for that reason that the courts have not permitted the laymen to place the label upon their ailments. They may discuss and they may detail the nature of the ailment, the pains they have, the obvious effect upon them, and that sort of thing, but otherwise not, and that was the reason for the Court sustaining those objections.

"Now, certain evidence in this case has consisted in the testimony of scientists, including medical men. Some of these testified to their personal observations of the results of ozone when used on human patients, some on experimental animals and on bacteria. There was testimony pertaining to a scientific determination of the emissions which the device is capable of producing. The facts established by recognized scientific investigations conducted by fair-minded, well-qualified scientific experts are deserving of high standing.

"Ordinarily in the trial of cases witnesses are confined in their testimony to facts within their personal knowledge. They are not permitted to draw conclusions or express opinions. There is an exception to that rule, however, which is this: that when the points in issue are concerned with a particular subject matter with respect to which there are trained persons who have special education, training and experience in a particular field, such persons are known as 'experts' and because of their special education, training and experience, are permitted to express opinions. That is particularly true with respect to matters with which the public generally does not and cannot completely familiarize itself. There are certain things that you and I as laymen cannot know. We haven't the faculties for knowing, so in those cases expert testimony is accepted by the Court where those who are trained and have made experiments may give to the jury and to the Court the benefit of their experiences and of their investigations and research.

"You are required, of course, to weigh and evaluate the testimony of an expert witness precisely as you weigh and evaluate the testimony of any non-expert witness. That is, you will consider the probability and reasonableness of the things to which the expert has testified, his interest in the outcome of the case, his education, training and experience, his standing in the profession, or want of it, and the breadth of his experience in the subject matter which would enable him to arrive at a correct conclusion. In this regard you should ask yourself: Is this witness, as a matter of fact, an expert qualified by scientific education, training and experience to acquaint himself with the scientific facts?

"You are the sole judges of the credibility of the witnesses and of the weight and value you will give to a witness' testimony. In determining the weight and value to be given to the testimony of any witness, you may take into consideration the attitude and demeanor of the witness on the stand; the willingness or unwillingness, as shown by the evidence of the witness, to speak truthfully with respect to matters within the knowledge of such witness; the opportunity the witness had to know and to be informed with respect to the matters about which such witness gives testimony; the interest of the witness, if any, in the result of the trial, as shown by the evidence; the reasonableness or unreasonableness, in your opinion, of the witness' testimony; the feeling on the part of the witness for or against either party as shown by the evidence, and any other fact or circumstance which you may consider important in weighing the witness' testimony. If you conclude that any witness has wilfully sworn falsely to any material fact, you are at liberty to disregard the whole or any part of such witness' testimony. I do not make that statement to you, ladies and gentlemen of the jury, as indicating any state of mind on the part of the Court as to whether a witness has testified falsely or otherwise. It is simply a guide that may be used by you in weighing the testimony and the evidence when you have gone to your jury room.

"The intent with which J. C. Gage, the claimant, acted in making the shipments is not a question for your consideration in this case. The government is not required to prove a wrongful intent or an awareness of wrongdoing. It is not necessary for you to find that J. C. Gage intended to make false or misleading statements in the labeling. The question of whether Mr. Gage acted in good faith is not material in this case. It is sufficient for a finding for the Government that the statements complained of, or any one of them, be false or misleading regardless of whether Mr. Gage was aware that any one of the statements was false or misleading. The persuasive effect of a false or misleading statement in labeling on the reader's mind is the same whether the representations were made in good faith or not. It is the responsibility of the person who uses the channels of interstate commerce for the distribution of devices to be assured that the labeling of the devices contain no false or misleading statement or representation. The statute places the burden of acting, at their own risk, upon persons who ship devices. It does not place the risk of use of devices upon the public, who are largely helpless in this regard.

"You are instructed that the devices here involved were misbranded if you are satisfied that the government has proved by a fair preponderance of the credible evidence that any single statement made in the labeling, Government's Exhibits 2 and 3, regarding the effect of the devices when used according to directions in the cure, mitigation, treatment, or prevention of any of the

diseases, disorders, conditions, or symptoms enumerated in the various labels was either false or misleading. In this regard it is not necessary for you to find that every statement complained of by the government is false or misleading, but if the government has sustained its contention in regard to any one of them, then it would be your duty to render a verdict in its favor.

"On the contrary, you are instructed that the issue in this case is whether the representations as set forth in the printed circulars delivered to the purchasers of the Ozone generator are false and misleading in any particular, and if the jury finds that said circulars are not false and misleading in any particular, then the jury should find for the claimant.

"This case does not involve a fine or penalty of any kind against the claimant. In the event there is a verdict favorable to the government in this case the devices are forfeited to the government and the law imposes the duty upon the Court of disposing of the devices and labeling involved. You are not to concern yourselves with that. The function of the jury is to weigh all of the evidence and determine whether you should render a verdict for the claimant or the government.

"It requires twelve of your number agreeing to return a verdict. When you have gone to your jury room, you will elect, of course, a foreman from among your number and when you have arrived at a verdict, your verdict will be signed by the foreman.

"This case has taken, ladies and gentlemen, approximately four days to try. Every possible effort should be made by the jury to arrive at a verdict. All of the evidence has been submitted apparently that can be submitted. Each side is represented by able and distinguished counsel. The case has been tried well and it is not likely that it could ever be tried any better. The jury to which it is being tried is drawn from the same source and in the same manner that any other jury would have to be drawn that might in the future be called upon to try this case, or any case like it. No juror should sacrifice his or her own convictions or do that which they believe, under their oath, should not be done, but, on the contrary, they should be respectful of each other's opinion and listen with the idea of conviction and make every effort consistent with your oath and your own conscience to finally arrive at a verdict.

"There have been prepared for your consideration seven verdicts. They will be handed to the bailiff when you retire and be delivered to you in your jury room. There are 7 cases that are being tried here, as was told you in the beginning. They are identical, so there should be 7 verdicts to be signed by you, one in each case. The verdict reads, 'We, the jury in the above entitled case'—and I have clipped them together—'We, the jury in the above entitled case, find the issues in favor of the Government and against the Claimant,' and a place for the foreman to sign. If you find for the Claimant, the verdict will read, 'We, the jury in the above entitled case, find the issues in favor of the Claimant and against the Government,' to be signed by the foreman, so that there will be 7 verdicts and they are numbered so that there should be no confusion with respect to them.

"I believe I have covered the case. The jury will retire for just a little while—let's see, you don't want to go out now, I am sure. It will take you some time so I suggest you come back, ladies and gentlemen, after lunch. When do you want to come back, one o'clock or one-thirty, whatever time you want to come back."

"A JUROR. One o'clock."

"The COURT. Very well. Under the instructions heretofore given you, you will be excused until one o'clock and return to the jury box at that time."

(Whereupon, the jury being excused, the following further proceedings were had:)

"The COURT. Gentlemen, what exceptions do you have to take to the charge of the Court?"

"Mr. HARGUS. None, your Honor."

"The COURT. What about you, Mr. Prince?"

"Mr. PRINCE. Your Honor, we wish to except to one part of your charge and that is where you selected a class of the witnesses and commented upon their credibility."

"The COURT. That is with respect to the—"

"Mr. PRINCE. Experts."

"The COURT. Very well, the exception will be allowed. We will now adjourn until one o'clock."

(Whereupon, the Court stood at recess until one o'clock p. m.)

(And, thereafter, at one o'clock p. m., the jury retired to consider of its verdict, and at two-thirty o'clock p. m., returned to the court room for further instructions as follows:)

"The COURT. The jury has requested some clarification of some instructions that they are in doubt about and have asked to have them brought into the court room."

"Mr. CELL. Beg pardon?"

"The COURT. The jury wants some clarification of one of the instructions and I have asked them to be brought back."

"Mr. CELL. I don't see any objection to that."

"The COURT. Mr. Foreman, the bailiff informs me that there is some question—misunderstanding probably, concerning some instructions. Will you advise the Court?"

"The FOREMAN. Well, your Honor, a question has arisen, when you gave us the charge of the law as to one part, as to what we were to consider, and this part that has come up—we asked if we were to consider whether or not the machine helps to relieve, medicate in any way, or are we to rely upon the literature that accompanies the machine?"

"The COURT. You are to consider—let me see if I can find that instruction. I should like to give it to you as I gave it to you this morning. Here was the instruction I gave you this morning. You are instructed that the devices here involved were misbranded, if you are satisfied that the Government has proven by a fair preponderance of the credible evidence that any single statement made in the labeling, Government Exhibits 2 and 3, regarding the effect of the devices when used according to directions in the cure, mitigation, treatment or prevention of any of the diseases, disorders, conditions or symptoms enumerated in the various labels was either false or misleading. In this regard it is not necessary for you to find that every statement complained of by the Government is false or misleading, but if the Government has sustained its contention in regard to any one of them, then it would be your duty to render a verdict in its favor. In other words, if the jury finds that there is any misrepresentation with respect to any of the information with regard to this machine. Now, anything further that the Court can give you within the limits of the Court's authority I shall be glad to do so. If you find there is any misrepresentation with respect to any of the information that is before you, then it would be your duty to find for the plaintiff, the United States. Is there any misunderstanding in the mind of any person before you go back?"

"The FOREMAN. Thank you, your Honor."

"The COURT. You think that clears it up?"

"The FOREMAN. I think so."

"The COURT. Is there any exception to that?"

"Mr. CELL. I think not."

"The COURT (to the jury). Just stand outside until counsel has been given an opportunity to take exceptions."

(Whereupon, the jury retired and the following proceedings were had out of the presence and hearing of the jury:)

"Mr. HARGUS. There is none on the part of the Government."

"The COURT. Any exceptions, Mr. Cell?"

"Mr. CELL. I think not, your Honor."

"The COURT. Very well. I read the instructions exactly as it was read to them today. Very well, let them go."

(Whereupon, the jury retired to further consider of its verdict.)

(And thereafter, at 2:50 o'clock p. m., the jury returned into open court, and the following proceedings were had:)

"The COURT. [Reading:] We, the jury in the above entitled cause, find the issues therein in favor of the Government and against the Claimant.

—Howard R. Victor, Foreman."

"Is that the verdict of the jury, ladies and gentlemen, and each and every member of the jury?"

"The FOREMAN. Yes, sir."

"The COURT. In 5937, that is the same in each and every verdict of the seven cases. Do you gentlemen want me to read them all?"

"Mr. CELL. I don't think that is at all necessary."

"The COURT. Ladies and gentlemen, is that the verdict of the jury in each and every one of the cases in which you have returned verdicts, 5476, 5935, 5936, 5937, 5938 and 5939, is that the verdict in each and every one of those cases?"

"The FOREMAN. Yes, sir."

"The COURT. Thank you, ladies and gentlemen of the jury. Do you care to have the jury polled?"

"Mr. CELL. No, your Honor."

"The COURT. Record the verdict, Mr. Clerk, in the seven cases before the Court."

The jury returned a verdict in favor of the Government, and on November 29, 1949, judgment of condemnation was entered and the court ordered that the devices and the labeling be delivered to the Food and Drug Administration.

2988. Misbranding of Roll-A-Ray. U. S. v. 228 Cartons * * *. (F. D. C. No. 26076. Sample No. 8621-K.)

LIBEL FILED: November 18, 1948, Southern District of New York.

ALLEGED SHIPMENT: On or about February 11, 1948, by the O. A. Sutton Corp., from Wichita, Kans.

PRODUCT: 228 cartons each containing 12 *Roll-A-Ray* devices at New York, N. Y. Examination showed that the device consisted of a brown plastic molded case with handle attached. The case enclosed a light bulb and two rubber rollers placed at either end of the bottom part of the case. The rollers contacted the body for massaging purposes, and the light bulb furnished heat. A plastic grid was fitted over the bulb to protect the body from contact with the lamp.

LABEL, IN PART: "Roll-A-Ray Heat Massage With Infra Red."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading since heat and massage are not adequate treatments for the purposes represented: "For Home Reducing and an Aid in the Relief of Discomforts Arising from Rheumatism, Lumbago, Muscular Aches, Physical Aches * * * for Health and Beauty * * * to remove fatty tissues."

DISPOSITION: June 9, 1949. Elcord Products Corp., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond, conditioned that each device be modified by removing the 60-watt bulb contained therein and replacing it with a 30-watt bulb; by placing a foil reflector on the inner portion of the device; by covering, removing, or destroying the labeling of directions and uses contained in the labeling of the device; and by using labeling approved by the Food and Drug Administration, so as to comply with the requirements of the law.

DRUGS FOR VETERINARY USE*

2989. Misbranding of Calfurdine. U. S. v. 2 Cans, etc. (F. D. C. No. 26384-Sample No. 28671-K.)

LIBEL FILED: January 7, 1949, District of Utah.

ALLEGED SHIPMENT: On or about July 22 and August 5, 1947, by the Germ-O-Tone Laboratories, from Phoenix, Ariz.

*See also No. 2973.

PRODUCT: 2 5-gallon cans, 12 1-gallon jugs, 21 ½-gallon jugs, 28 1-quart bottles, 17 16-ounce bottles, and 65 8-ounce bottles of *Calfurdine* at Provo, Utah. Analysis indicated that the product was essentially a solution of calcium polysulfide and iodine.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading since they represented and suggested that the article when used as directed was effective in the prevention and treatment of disease conditions of poultry and animals, whereas the article when used as directed was not effective for such purposes: "*Calfurdine* * * * Directions: Chicks and Poults—Give one teaspoonful in each quart of Drinking Water Growing and Adult Chickens, Turkeys, Hogs, Cattle, Horses, Rabbits, Pigeons, Sheep, Fox, Mink—Give one tablespoonful in each gallon of Drinking Water Growing and Adult Dogs: Mix one-fourth to one-half teaspoonful (depending on age and size of dog) in ground, fresh meat—Give once daily. Wet Mash Treatment: If you have dew drop or continuous automatic water systems, or if poultry or livestock refuse to take it in the drinking water, mix wet mash as follows: Use two tablespoons to a gallon of water. Use this treated water to make a moist, crumbly mash and feed this at least two or three times daily, in amounts that will be eaten in about 5 minutes time. Keep all other feed away when this treatment is given—Give this treatment for at least 12 consecutive days—For Best Results Use Regularly."

DISPOSITION: On June 8, 1949, a motion was filed by the Germ-O-Tone Laboratories, claimant, for dismissal of the libel upon the ground that the libel failed to state a claim upon which the relief prayed for could be granted. On November 25, 1949, the motion to dismiss was heard by the court and denied. Thereafter the claimant filed an answer denying that the product was misbranded, which answer was subsequently withdrawn, and on January 12, 1950, judgment of condemnation was entered and the court ordered that the product be destroyed.

2990. Misbranding of Dr. Martin's Sulfadine, Dr. Martin's Sulfa Du, and Dr. Martin's Avizine. U. S. v. 168 Bottles, etc. (F. D. C. No. 27791. Sample Nos. 53533-K to 53538-K, incl.)

LABEL FILED: August 26, 1949, Western District of Louisiana.

ALLEGED SHIPMENT: Between the approximate dates of December 21, 1948, and June 9, 1949, by the Hill Poultry Service, from Dallas, Tex.

PRODUCT: 168 bottles of *Dr. Martin's Sulfadine*, 247 bottles of *Dr. Martin's Sulfa Du*, and 473 bottles of *Dr. Martin's Avizine* at Shreveport, La., together with a number of leaflets entitled "Dealer price list February, 1949, Dr. Martin's Poultry Medicines," and a number of booklets entitled "Dr. Martin's Original Hydrochloride Liquid Sulfas."

Analyses of the products indicated that they had approximately the compositions stated on their labels. The bottles of the products ranged in size from 4 ounces to 1 gallon.

LABEL, IN PART: "Dr. Martin's Sulfadine * * * Sulfaguanidine * * * 18 gr. per fl. oz. * * * Directions: Add two tablespoonfuls (one ounce) to each gallon of all drinking water. For severe cases continue treatment for five full days," "Dr. Martin's Sulfa Du * * * Sulfathiazole * * * 22.2 gr. per fl. oz. * * * Directions: Add two tablespoons (1 oz.) to each

gallon of all drinking water. Continue treatment for five days, discontinue three days and repeat only if necessary," and "Dr. Martin's Avizine * * * Sulfamethazine, Sulfathiazole * * * 14.4 gr. per oz. * * * Directions: For preventative measures and general drinking water use add 2 table-spoons to each gal. of drinking water during the first 5 to 7 days."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle labels and in the accompanying leaflets and booklets were false and misleading since the statements represented and suggested that the *Dr. Martin's Sulfadine* when used as directed was effective to control cecal coccidiosis in poultry; that the *Dr. Martin's Sulfa Du* when used as directed was effective to control colds or coryza of fowls and to reduce the severity of attacks of virus infections such as bronchitis, fowlpox, and Newcastle disease; and that the *Dr. Martin's Avizine* was effective to prevent early mortality in baby chicks and deaths from *Salmonella pullorum*, to aid in the control of pullorum disease and other mixed bacterial infections of baby chicks, and to control fowl cholera. The articles when used as directed were not effective for such purposes.

DISPOSITION: October 18, 1949. Default decree of condemnation and destruction.

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¹ (2987) Seizure contested. Contains charge to the jury.

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¹ (2987) Seizure contested. Contains charge to the jury.



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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

2991-3000

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

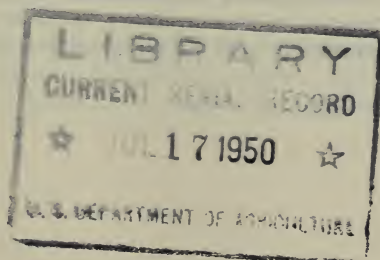
PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., May 24, 1950.

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DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

2991. Misbranding of Gold-N-Ray Eucalyptus Oil Liniment. U. S. v. Edward N. Golden (Golden Boy Distributing Co.), and Dorothy D. Golden (Dorothy D. Dickstein). Pleas of guilty. Fine of \$500 against each defendant. (F. D. C. No. 25590. Sample No. 19602-K.)

INFORMATION FILED: February 9, 1949, Eastern District of Michigan, against Edward N. Golden, trading and doing business as the Golden Boy Distributing Co., at Detroit, Mich., and against Dorothy D. Golden, also known as Dorothy D. Dickstein, who was associated with Edward N. Golden in the conduct of the business.

ALLEGED SHIPMENT: Between the approximate dates of May 5 and 15, 1948, from the State of Michigan into the State of Ohio.

PRODUCT: Analysis disclosed that the product contained some eucalyptus oil and menthol in a high boiling oil, probably mineral oil.

LABEL, IN PART: "Gold-N-Ray Eucalyptus Oil Liniment * * * The Golden Boy Dist. Co. 85 Walton Street Brooklyn, New York."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement on the bottle label "Eucalyptus Oil Liniment" was false and misleading. The statement represented and suggested that the article consisted of eucalyptus oil, whereas it consisted of volatile oils, including eucalyptus and peppermint oils, approximately 28 percent, and nonsaponifiable oil such as petroleum oil, approximately 72 percent.

Further misbranding, Section 502 (a), certain statements in accompanying circulars entitled "Gold-N-Ray Eucalyptus Compound" were false and misleading since they represented and suggested that the article was a refined and improved distillate from eucalyptus leaves; that it possessed the power of producing and maintaining health and energy; that it would exhibit miraculous properties; that in vapor form it would cleanse and disinfect the air and banish malaria, yellow fever, and epidemic fever; that it would play an important part in keeping one well; that it was of value in keeping the body sound, sturdy, and safe against infection and many common ailments; that it was a powerful antiseptic; that it would be efficacious in the treatment of asthma and catarrhal conditions; and that it would give beneficial results in cases where stimulation and disinfection were needed. The article was not a refined and improved distillate from eucalyptus leaves but consisted of volatile oils and nonsaponifiable oil, as indicated above; it was not a powerful antiseptic; and it would not fulfill the promises of benefit stated and implied.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of hay fever, sinus affections, colds, sore throat, asthma, neuritis, arthritis, and rheumatism, which were the diseases, symptoms, and conditions for which the article was intended to be used.

DISPOSITION: On November 21, 1949, the defendants filed a consent for transfer of the case to the Southern District of New York for pleading and sentence. Thereafter, pleas of guilty were entered by the defendant, and on January 24, 1950, the court imposed a fine of \$500 against each defendant.

2992. Misbranding of Gold-N-Medal Foot Balm. U. S. v. Edward N. Golden (Golden Boy Distributing Co.), and Dorothy D. Dickstein (Dorothy D. Golden). Pleas of guilty. Imposition of sentence suspended and defendants placed on probation for one year. (F. D. C. No. 26751. Sample No. 13668-K.)

INFORMATION FILED: October 19, 1949, Middle District of Pennsylvania, against Edward N. Golden, trading as the Golden Boy Distributing Co., Brooklyn, N. Y., and Dorothy D. Dickstein, also known as Dorothy D. Golden, who was associated with Edward N. Golden in the conduct of the business.

INTERSTATE SHIPMENT: On or about July 12, 1949, from Brooklyn, N. Y., to Wilkes-Barre, Pa.

LABEL, IN PART: "The Gold-N-Medal Foot Balm Contains Lanolin, Stearic Acid, Camphor, Menthol, Methyl Salicylate And Eucalyptus Oil * * * Distributed By The Golden Boy Dist. Co. 85 Walton St., Brooklyn, N. Y."

ALLEGED VIOLATION: On or about July 26, 1949, while the article was held for sale after shipment in interstate commerce, the defendants, at a demonstration held at Wilkes-Barre, Pa., prescribed, recommended, and suggested by oral statements, uses of the article for various diseases, symptoms, and conditions mentioned, for which adequate directions for use did not appear in the labeling of the article, which acts resulted in the article being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of arthritis, neuritis, sciatica, rheumatic aches and pains, varicose veins, shoulder pains, any ache and pain, ingrown toe nails, eczema, skin rash, and blemishes, which were the diseases, symptoms, and conditions for which the article was prescribed, recommended, and suggested by the defendants, as indicated above.

DISPOSITION: On November 17, 1949, a consent was filed by the defendants to the transfer of the case to the Southern District of New York for plea and sentence. Thereafter, pleas of guilty were entered by the defendants, and on January 24, 1950, the court suspended the imposition of sentence and placed the defendants on probation for 1 year.

2993. Misbranding of X-ray device. U. S. v. 1 Device * * * (and 1 other seizure action). (F. D. C. Nos. 25979, 26030. Sample Nos. 25514-K, 26980-K.)

LABELS FILED: November 2 and 12, 1948, District of Minnesota and Eastern District of Missouri.

ALLEGED SHIPMENT: 1 device was shipped on or about March 27, 1946, by J. S. Peterson, from Chicago, Ill., and another device was shipped on or about October 30, 1946, by Keat, Inc., from Chicago, Ill. In addition, a number of circulars were shipped by the latter firm during July 1947.

PRODUCT: 1 X-ray device at St. Louis, Mo., and 1 X-ray device, together with a number of circulars entitled "Vienna Brings You a New Discovery," at Minneapolis, Minn. Examination showed that the device was an X-ray machine consisting of a Fischer Control Stand, a transformer, and an X-ray tube.

LABEL, IN PART: (On cabinet) "Fischer Type R. Amp 12 Cycle 60 Volts 110 No. 27462" and "Fischer Type S. Amp 35-20 Cycle 60 Volts 110-220 No. 25001"; (on X-ray head) "Type 6-TG-2 Eureka No. 1108 [or "1096]."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use; and, Section 502 (f) (2), the labeling failed to bear such adequate warnings against unsafe dosage and methods and duration of administration and application, in such manner and form as are necessary for the protection of users.

Further misbranding, Section 502 (a), the following statements in the circulars accompanying the Minnesota device were false and misleading since the use of X-ray for removal of hair is not safe and may result in irreparable damage to the skin: "The Keat method of removing superfluous hair is not only * * * harmless, but it is * * * safest method known to science * * * There is no case on record of the slightest injury ever having resulted from the treatment. The skin is left clean, clear, and unblemished as nature intended it to be and remains so forever afterward."

DISPOSITION: The Keat Salon of Minneapolis and Keat Salon, Inc., of St. Louis, appeared as claimants in the respective actions and filed answers denying that the devices were misbranded. Thereafter, upon application of the claimants, the actions were removed and consolidated for trial in the Northern District of Indiana.

On April 6, 1950, the claimants having withdrawn their claims and answers, judgments of forfeiture were entered and the court ordered that the devices be delivered to a United States Government Hospital, on condition that the devices be recalibrated and modified in accordance with the directions and suggestions of the Federal Security Agency.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

2994. Adulteration of Geo-Mineral. U. S. v. 89 Bottles * * * (and 18 other seizure actions). (F. D. C. Nos. 27062, 27063, 27071, 27074, 27089, 27097, 27120 to 27122, incl., 27128, 27130, 27202, 27203, 27231, 27241, 27263, 27318, 27383, 27392. Sample Nos. 5234-K, 5235-K, 5764-K, 19334-K, 19852-K, 19853-K, 25692-K, 25852-K, 25853-K, 29274-K, 29275-K, 36730-K, 36732-K, 36734-K, 41045-K, 41063-K, 41920-K, 49185-K, 49186-K, 51655-K, 58024-K, 58029-K.)

LIBELS FILED: Between April 26 and June 17, 1949, District of Minnesota, Northern District of Ohio, Middle District of Tennessee, Northern District of Illinois, Southern District of Iowa, District of Colorado, District of Oregon, District of Montana, District of Maine, District of Arizona, and District of Massachusetts.

ALLEGED SHIPMENT: Between the approximate dates of October 28, 1948, and April 21, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

PRODUCT: 7,767 3-ounce bottles of *Geo-Mineral* at Minneapolis and St. Paul, Minn., Cleveland and Lima, Ohio, Nashville, Tenn., Chicago, Ill., Des Moines, Iowa, Denver and Pueblo, Colo., Portland and Medford, Oreg., Butte and Missoula, Mont., Portland, Maine, Phoenix, Ariz., and Boston, Mass. Examination showed that the product was a water solution of ferric sulfate and was contaminated with mold.

LABEL, IN PART: "Geo-Mineral * * * Sole Distributor Geo-Mineral Company, St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

DISPOSITION: Between June 29 and September 8, 1949. Default decrees of condemnation and destruction.

2995. Adulteration of Geo-Mineral. U. S. v. 72 Bottles * * * (and 19 other seizure actions). (F. D. C. Nos. 27072, 27098, 27119, 27125, 27236, 27268, 27273 to 27275, incl., 27288 to 27290, incl., 27299, 27305, 27308, 27382, 27398, 27399, 27471, 27655. Sample Nos. 1449-K, 1450-K, 1453-K, 1465-K, 1467-K, 1563-K, 1841-K, 1842-K, 3281-K, 5238-K, 19336-K, 44289-K, 44294-K, 44300-K, 47606-K, 51572-K, 51807-K, 56066-K, 63681-K, 64313-K.)

LABELS FILED: Between April 26 and July 20, 1949, Northern and Southern Districts of Ohio, Eastern and Western Districts of Virginia, District of Maine, Western District of South Carolina, Middle and Western Districts of North Carolina, Southern District of Florida, Eastern District of Tennessee, District of Kansas, and District of North Dakota.

ALLEGED SHIPMENT: Between February 1949, and May 12, 1949, from Atlanta, Ga., and St. Louis, Mo., by the Geo-Mineral Co.

PRODUCT: 6,132 bottles of *Geo-Mineral* at Akron, Cincinnati, and Columbus, Ohio; Norfolk and Roanoke, Va.; Portland, Maine; Greenville and Spartanburg, S. C.; Charlotte and Greenboro, N. C.; Miami and Jacksonville, Fla.; Knoxville, Tenn.; Wichita, Kans.; and Bismarck, N. Dak.

Examination showed that the product was a water solution of ferric sulfate and was contaminated with mold.

LABEL, IN PART: "Geo-Mineral 3 Fluid Ounces Net Contents."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

DISPOSITION: Between June 29 and November 7, 1949. Default decrees of condemnation and destruction.

2996. Adulteration and misbranding of Geo-Mineral. U. S. v. 538 Bottles * * * (F. D. C. No. 27221. Sample No. 50602-K.)

LABEL FILED: May 20, 1949, Eastern District of Washington.

ALLEGED SHIPMENT: On or about March 25 and 29, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

PRODUCT: 538 3-ounce bottles of *Geo-Mineral* at Yakima, Wash., in the possession of Payless Drug. Analysis showed that the product was a water solution of ferric sulfate and was contaminated with mold.

LABEL, IN PART: "Geo-Mineral * * * Sole Distributor Geo-Mineral Company St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold. The article was adulterated when introduced into and while in interstate commerce.

Misbranding, Section 502 (a), certain statements in the labeling of the article, namely, in the newspaper advertisement which was on display with the article, were false and misleading. The statements represented and suggested that the article was effective in the treatment of stomach ailments, weak kidneys, rheumatic pains, arthritis, neuritis, headaches, nervousness, toxins, bloating, lack of vitality and energy, poor appetite, underweight, dizzy

spells, and rheumatism, and that the article would make one feel, eat, sleep, work, and enjoy life better. The article was not effective in the treatment of the conditions nor for the purposes mentioned. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 11, 1949. Default decree of condemnation and destruction.

2997. Adulteration and misbranding of Geo-Mineral. U. S. v. 4 Cartons * * *.
(F. D. C. No. 26614. Sample No. 36858-K.)

LIBEL FILED: February 26, 1949, Western District of Washington; amended libel filed August 10, 1949.

ALLEGED SHIPMENT: On or about November 3, 1948, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

PRODUCT: 4 cartons, each containing 36 bottles, of *Geo-Mineral* at Hoquiam, Wash.

LABEL, IN PART: (Bottle) "Geo-Mineral 3 Fluid Ounces, Net Contents Ferric Sulphate $\text{Fe}_2(\text{SO}_4)_3$ and traces of other minerals. The mineral contents contained herein were leached with water from a natural clay. Dietary Iron Aid Two teaspoonfuls of this mineral extract will supply Twice the minimum daily adult Iron (Fe) requirement. Minimum daily adult requirement, 10 mgm. * * * Sole Distributor Geo-Mineral Company, St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

Misbranding, Section 502 (a), certain statements in an accompanying leaflet entitled "Good News for Sick People" were false and misleading. The statements represented and suggested that the article was effective for the treatment of sick people, stomach ailments, weak kidneys, rheumatic pain, arthritis, neuritis, headaches, nervousness, acid condition of the blood, toxins, bloating, lack of vitality or energy, poor appetite, underweight, dizzy spells, rheumatism, and kidney ailments; that it would help make one strong and full of pep, life, and energy; that it would generate mental brilliance, give sparkling eyes, fight disease, and build up health; that it would overcome dullness, laziness, absence of ambition to work or play, blue feeling, feeling old before one's time, weakening of sexual powers, seeming worthlessness of living, and wearing down with worry; that it would cleanse and purify the intestines, relieve gas, purify the kidneys, and relieve long continued suffering; that it would constitute an investment for health; and that it would enable one to feel, eat, sleep, work, and enjoy life better. The article was not effective for such purposes.

DISPOSITION: August 10, 1949. The Geo-Mineral Co. having appeared as claimant and later withdrawn its claim, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

2998. Misbranding of Homeopathic Combination Tablets, Kollesol Uterettes Tablets, Dr. Wise's Instant Relief and Tablets No. 1 and Tablets No. 2, Homeopathic Calcarea Fluor Tablets, Homeopathic Kali Mur Tablets,

*See also Nos. 2991, 2993, 2996, 2997.

Homeopathic Natrum Sulph Tablets, Maizoleo, Pix'Ema, and Wise's Kollesol Tablets. U. S. v. 8 Bottles, etc. (F. D. C. No. 27767. Sample Nos. 40845-K to 40854-K, incl., 40874-K to 40877-K, incl.)

LIBEL FILED: August 18, 1949, Western District of Washington.

ALLEGED SHIPMENT: Between the approximate dates of April 1 and June 8, 1949, by the Wise's Kansas City Homeopathic Pharmacy, from Kansas City, Mo.

PRODUCT: 8 250-tablet bottles of *Homeopathic Combination Tablets*, 3 25-tablet bottles of *Kollesol Uterettes Tablets*, 3 units, each containing 3 bottles, with one of the bottles labeled "Hay Fever * * * 1," one labeled "2," and one labeled "Dr. Wise's Instant Relief"; 1 5-pound carton of *Homeopathic Calcareo Fluor Tablets*; 2 5-pound cartons of *Homeopathic Kali Mur Tablets*; 2 5-pound cartons of *Homeopathic Natrum Sulph Tablets*; 5 1-pint bottles of *Maizoleo*; 3 1-ounce jars of *Pix'Ema*; and 4 300-tablet bottles of *Wise's Kollesol Tablets* at Seattle, Wash., together with a number of booklets entitled "Wise's Homeopathic Manual for Home Use."

Analyses showed that the *Homeopathic Combination Tablets* contained milk sugar, with traces of tin, calcium, and sulfur compounds; that each tablet of the *Kollesol Uterettes Tablets* contained boric acid, 8-hydroxyquinoline sulfate 0.71 gram, and zinc sulfate; that the bottles labeled *Dr. Wise's Instant Relief* contained oil of eucalyptus; that the bottles labeled *Tablets No. 1* contained tablets consisting essentially of milk sugar, with a small amount of silica and a trace of a chromium compound, and that the bottles labeled *Tablets No. 2* contained tablets consisting of milk sugar, with a minute amount of a sulfate; that the *Homeopathic Calcareo Fluor Tablets* contained milk sugar, with a minute amount of calcium fluoride; that the *Homeopathic Kali Mur Tablets* contained milk sugar, with a minute amount of potassium chloride; that the *Homeopathic Natrum Sulph Tablets* contained milk sugar, with a trace of sodium sulfate; that the *Maizoleo* contained approximately 2.7 percent of alcohol and water, with traces of extracts of plant drugs, calcium, magnesium, sodium, potassium, and phosphorus compounds; that the *Pix'Ema* was an ointment containing approximately 2.7 percent hydroxyquinoline sulfate, together with tar oil and zinc oxide; and that each tablet of *Wise's Kollesol Tablets* contained 21.6 milligrams of 8-hydroxyquinoline sulfate.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles and in the accompanying booklets were false and misleading since the articles would not be effective in the treatment of the conditions and for the purposes represented and implied. The statements represented and suggested:

That the *Homeopathic Combination Tablets* would be effective in the treatment of boils, carbuncles, pustular acne, styes, abscesses, and suppurating wounds, and that it would be effective to correct lowered resistance to staphylococcus;

That the *Kollesol Uterettes Tablets* would be effective in the treatment of female troubles, womb troubles, pelvic inflammatory conditions, acute local discharges, pruritus, and excoriation of the vulva, and that it would be effective to stimulate tender generative organs;

That *Dr. Wise's Instant Relief* and *Tablets No. 1* and *Tablets No. 2*, in combination, would be effective in the treatment of hay fever, colds in the head, acute catarrh, and influenza;

That the *Homeopathic Calcarea Fluor Tablets* would be effective in the treatment of backache, tumors, varicose veins, relaxed uvula, opacities of cornea, hard lumps in breast, ulcers, disease of eyes, piles, toothache, vomiting, constipation, prolapse, varices, aneurisms, catamenia, bone affections, glandular tumors, goiter, styes and swellings, respiratory organ affections, and simple hemorrhoids;

That the *Homeopathic Kali Mur Tablets* would be effective in the treatment of croup, diphtheria, dysentery, catarrh, coughs, deafness from catarrh, skin affections, glandular swellings, deafness, constipation, tonsillitis, white mucus, aphthae, bruises, sprains, burns, scalds, ulcers, worms, earache, dysmenorrhea, erysipelas, gum boil, hemorrhage, measles, mumps, nettle rash, pleurisy, rheumatism, scalp affections, leucorrhea, acne, biliousness, bunions and warts, catarrhal conditions, coughs following colds, indigestion caused by rich food, and diarrhea;

That the *Homeopathic Natrum Sulph Tablets* would be effective in the treatment of malaria, influenza, greenish diarrhea, jaundice, diabetes, asthma, polyuria edema, gout, hives, laryngitis, urinary trouble, biliousness, liver trouble, vomiting, intermittent fever, erysipelas, la grippe, acne, dropsy, headache, indigestion, sour stomach, bilious headaches, colds, colic, diarrhea, and disordered stomach with bilious symptoms;

That the *Maizoleo* would be effective in the treatment of bone disease, brain fag, debility, neurasthenia, coughs, weak lungs, bronchitis, lung trouble, loss of blood or animal fluids, nervous prostration from overwork, malnutrition, malassimilation, indigestion, diarrhea, constipation, loss of energy, leucorrhea, debilitating diseases, wasting diseases, weakness, and nervous prostration, and that it would be effective to enrich the blood and give new life, vigor, health, and flesh after la grippe;

That the *Pix'Ema* would be effective in the treatment of eczema and skin trouble, suppurative inflammation, and parasitic and pustular disease;

That the *Wise's Kollesol Tablets* would be effective in the treatment of nail in foot, rat or snake bite, burns, abrasions, septic wounds, carbuncles, cholera infantum, cholera morbus, threatening of constipation, chronic cough, diarrhea, dysentery, female troubles, ptomaine poisoning, toothache, foul breath and most serious conditions, and that it would be effective to destroy putrid matter and to inhibit pus.

Further misbranding, Section 502 (e) (2), *Dr. Wise's Instant Relief* was not designated by a name recognized in an official compendium and was fabricated from two or more active ingredients, and its label failed to bear the common or usual name of the article or of its active ingredients.

DISPOSITION: December 1, 1949. Default decree of condemnation and destruction.

2999. Misbranding of methionine tablets and vitamin P and C tablets. U. S. v. 5 Bottles, etc. (F. D. C. No. 28031. Sample Nos. 31940-K, 31941-K, 58060-K, 58061-K.)

LIBEL FILED: October 10, 1949, District of Arizona.

ALLEGED SHIPMENT: On or about March 2 and 29, June 17 and 22, August 1 and 15, and September 6, 1949, by the William T. Thompson Co., from Los Angeles, Calif.

PRODUCT: 5 100-tablet bottles, 2 50-tablet bottles, and 2 250-tablet bottles of *methionine tablets*, and 3 100-tablet bottles, 7 50-tablet bottles, and 1 250-tablet bottle of *vitamin P and C tablets* at Phoenix, Ariz.

LABEL, IN PART: "Thompson's Standardized Amino Acids d1-Methionine * * * Each tablet contains 7.7 grains (0.5 grams) of d1-Methionine" and "Thompson's * * * Vitamin P with Vitamin C * * * Three Tablets daily supply 600 mg. of Lemon Peel Infusion Dried and 30 mg. of Ascorbic Acid."

NATURE OF CHARGE: *Methionine tablets.* Misbranding, Section 502 (a), a statement in a leaflet entitled "Scientific Comment from the Research Laboratories Wm. T. Thompson Co. Methionine" which accompanied the article was false and misleading. This statement represented and suggested that there are disease conditions in humans caused by a deficiency of methionine, and that the article was effective in the treatment of subcortical hemorrhagic necrosis of the kidneys and decreased resistance to virus diseases. They are no known disease conditions of humans caused by a deficiency of methionine, and the article was not effective in the treatment of the diseases and conditions mentioned.

Vitamin P and C tablets. Misbranding, Section 502 (a), certain statements in an accompanying booklet entitled "Thompson's Vitamin Chart" and in an accompanying leaflet entitled "Scientific Comment from the Research Laboratories Wm. T. Thompson Co. Vitamin P" were false and misleading. These statements represented and suggested that apoplexy is due to a deficiency of vitamin P, and that vitamin P is an effective treatment for vascular purpura, psoriasis, and increased capillary fragility in hypertension, retinitis, and nephritis. Apoplexy is not due to a deficiency of vitamin P, and vitamin P is not an effective treatment for the conditions mentioned.

DISPOSITION: November 25, 1949. Default decree of condemnation and destruction.

3000. Misbranding of Magnetic Ray (device). U. S. v. 3 Devices * * *. (F. D. C. No. 27006. Sample Nos. 55126-K, 55127-K.)

LIBEL FILED: April 21, 1949, Western District of Oklahoma.

ALLEGED SHIPMENT: On or about November 18, 1948, by Frank Moran, from Dallas, Tex.

PRODUCT: 3 *Magnetic Ray* devices at Oklahoma City, Okla., together with a number of circulars entitled "Magnetic Ray Treatment," "Directions for taking Magnetic Ray Treatments," and "Magnetic Ray Company."

Mrs. Anna Mae Frances, who was the consignee of the devices, caused to be printed locally the circular entitled "Magnetic Ray Company." The other circulars were shipped to the consignee by Frank Moran.

Examination showed that the device consisted essentially of a coil of wire enclosed in a covering of imitation leather and made in the form of a belt. Attached to the device was an electric cord which was to be plugged into an ordinary lighting current outlet.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars accompanying the devices were false and misleading. The statements represented and suggested that the device was effective in the treatment of arthritis, asthma, anemia, bronchitis, bladder trouble, Bright's disease, colds, catarrhal deafness, catarrh, constipation, diabetes, eczema, epilepsy, goiter, headaches, hemorrhoids, heart diseases, high blood pressure, indigestion, insomnia, impotency, low blood pressure, lumbago, painful menstruation, neuralgia, neuritis, nervous troubles, obesity, paralysis, rheumatism, sciatica, tumors, tuberculosis, varicose veins, ulcers, and sinus trouble; that the device

would increase the elimination of poisons and assist in the removal of toxic conditions; that it would promote and equalize circulation of the blood and relieve congestion in every part of the body; that it would be effective in the relief of pain and other distressing physical sensations; that it would produce marked relaxation and promote sound and refreshing sleep; that it would stimulate a normal functioning of the various glands and other organs of the body; that it would overcome fatigue, increase efficiency both physical and mental, and exert a revitalizing influence upon the sexual or procreative glands; and that it would clear the complexion. The device would not be effective for the purposes represented.

The device was misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: Mr. J. E. Frances appeared as claimant for one of the devices and denied that the device was misbranded. No claimant appeared for the other devices involved in the action. A motion for summary judgment was filed on behalf of the Government, and on January 18, 1950, the motion was sustained. The court found that the devices and the labeling in the instant action were identical with the devices and labeling involved in the cases reported in notices of judgment on drugs and devices, Nos. 518 and 1339. Consequently, the court found that the issue of misbranding was *res judicata* and that the devices involved in the instant action were articles that had theretofore been adjudged to be misbranded. Accordingly, judgment of condemnation was entered, and the court ordered that the devices and the labeling be destroyed.

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PRODUCTS

	N. J. No.		N. J. No.
Devices	2293, 3000	Magnetic Ray (device)	3000
Geo-Mineral	2994-2997	Maizoleo	2998
Gold-N-Medal Foot Balm	2992	Methionine tablets	2999
Gold-N-Ray Eucalyptus Oil Liniment	2991	Pix'Ema	2998
Homeopathic Calcarea Fluor Tablets, Homeopathic Combination Tablets, Homeopathic Kali Mur Tablets, and Homeopathic Natrum Sulph Tablets	2998	Vitamin preparations	2999
Kollesol Tablets and Kollesol Uterettes Tablets	2998	Wise's, Dr., Instant Relief and Tablets No. 1 and Tablets No. 2	2998
		Kollesol Tablets	2998
		Women's disorders, remedy for ..	2998
		X-ray device	2993

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N. J. No.		N. J. No.
Dickstein, D. D.:		Peterson, J. S.:	
Gold-N-Medal Foot Balm-----	2992	X-ray device-----	2993
Frances, Mrs. A. M.:		Thompson, William T., Co.:	
Magnetic Ray (device)-----	3000	methionine and vitamin P and	
Geo-Mineral Co.:		C tablets-----	2999
Geo-Mineral-----	2994-2997	Vi-Jon Laboratories, Inc.:	
Golden, D. D.:		Geo-Mineral-----	2994, 2996, 2997
Gold-N-Ray Eucalyptus Oil		Wise's Kansas City Homeopathic	
Liniment-----	2991	Pharmacy:	
Golden, E. N.:		Homeopathic Combination Tab-	
Gold-N-Medal Foot Balm-----	2992	lets, Kollesol Uterettes Tab-	
Gold-N-Ray Eucalyptus Oil		lets, Dr. Wise's Instant Re-	
Liniment-----	2991	lief and Tablets No. 1 and	
Golden Boy Distributing Co.		Tablets No. 2, Homeopathic	
See Golden, E. N.		Calcarea Fluor Tablets, Ho-	
Keat, Inc.:		meopathic Kalir Mur Tab-	
X-ray device-----	2993	lets, Homeopathic Natrum	
Moran, Frank:		Sulph Tablets, Maizoleo,	
Magnetic Ray (device)-----	3000	Pix'Ema, and Wise's Kolle-	
Payless Drug:		sol Tablets-----	2998
Geo-Mineral-----	2996		



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<i>Business Credit</i>	<i>Public Contracts</i>
<i>Communications</i>	<i>Public Lands</i>
<i>Customs</i>	<i>Securities</i>
<i>Fair Trade Practice</i>	<i>Shipping</i>
<i>Food and Drugs</i>	<i>Social Security</i>
<i>Foreign Relations and Trade</i>	<i>Taxation</i>
<i>Housing</i>	<i>Transportation</i>
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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3001-3020

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

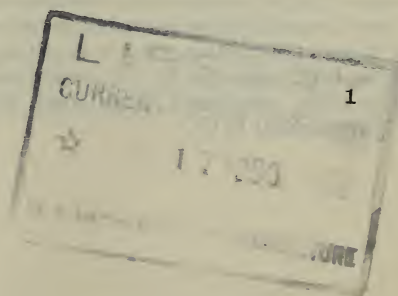
PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., June 8, 1950.

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*For presence of a habit-forming narcotic without warning statement, see No. 3002; contamination with filth, No. 3003; omission of, or unsatisfactory, ingredients statements, Nos. 3001, 3002; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3001, 3002; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3001, 3002.



DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3001. Misbranding of amphetamine hydrochloride tablets. U. S. v. Charles R. Wirth (Wirth Drug Store). Plea of nolo contendere. Fine, \$300; defendant placed on probation for 1 year. (F. D. C. No. 28098. Sample Nos. 22021-K, 23668-K, 23987-K, 53665-K.)

INFORMATION FILED: November 15, 1949, Eastern District of Louisiana, against Charles R. Wirth, trading as the Wirth Drug Store, New Orleans, La.

INTERSTATE SHIPMENT: Between the approximate dates of November 29, 1948, and January 19, 1949, from Chicago, Ill.

ALLEGED VIOLATION: On or about March 8 and April 4 and 6, 1949, and while a number of *amphetamine hydrochloride tablets* were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets to be repackaged and sold to various persons, which acts of the defendant resulted in the repackaged *amphetamine hydrochloride tablets* being misbranded. Each container of the repackaged tablets was unlabeled.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the containers of the repackaged *amphetamine hydrochloride tablets* bore no label containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; Section 502 (e) (1), the containers bore no label containing the common or usual name of the tablets, namely, "Amphetamine Hydrochloride"; and, Section 502 (f) (2), the containers bore no labeling containing warnings against use of the tablets in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: February 1, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$100 on each of the first three counts of the information, suspended the imposition of sentence on count four, and placed the defendant on probation for 1 year.

3002. Misbranding of Benadryl capsules, sulfathiazole lozenges, and phenobarbital tablets. U. S. v. Argus Chaffin (West End Drug Store), and Cleo Wear. Pleas of nolo contendere. Defendants placed on probation for 1 year. (F. D. C. No. 26712. Sample Nos. 27036-K, 27045-K, 27049-K.)

INFORMATION FILED: June 21, 1949, Western District of Arkansas, against Argus Chaffin, trading as the West End Drug Store, Fort Smith, Ark., and Cleo Wear, a pharmacist.

INTERSTATE SHIPMENT: On or about October 3, 1947, and May 7 and October 4, 1948, from the States of Missouri and Indiana into the State of Arkansas.

LABEL, WHEN SHIPPED: "Kapseals Benadryl Hydrochloride [or "Lozenges Sulfathiazole" or "Phenobarbital Tablets"] * * * Caution: To be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about August 31, September 27, and October 4, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused certain quantities of the drugs to be removed from the bottles in which they had been shipped and to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded. The repackaged *Benadryl capsules* were unlabeled. The other repackaged drugs were labeled "Sulfathiazole Lozenges" and "Phenobarbital ½ Gr."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs bore no label containing a statement of the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they bore no labels containing a statement of the quantity of the contents; and, Section 502 (f) (1), they bore no labeling containing directions for use.

Further misbranding, Section 502 (e) (1), the container of the repackaged *Benadryl capsules* bore no label containing the common or usual name of the drug; and, Section 502 (f) (2), the container of the repackaged *sulfathiazole lozenges* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

Further misbranding, Section 502 (d), the *phenobarbital tablets* contained a chemical derivative of barbituric acid, which derivative has been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the label of the repackaged tablets failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: September 30, 1949. Pleas of nolo contendere having been entered, the court placed the defendants on probation for 1 year.

3003. Adulteration and misbranding of Geo-Mineral. U. S. v. 672 Bottles * * *.
(F. D. C. No. 27227. Sample No. 51436-K.)

LABEL FILED: May 18, 1949, Southern District of Indiana.

ALLEGED SHIPMENT: On or about February 15, 1949, by Vi-Jon Laboratories, Inc., from St. Louis, Mo.

PRODUCT: 672 3-ounce bottles of *Geo-Mineral* at Anderson, Ind. Examination showed that the product was a water solution of ferric sulfate and was contaminated with mold.

LABEL, IN PART: "Geo-Mineral * * * Sole Distributor Geo-Mineral Company, St. Louis 1, Mo."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold.

Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: August 8, 1949. Default decree of forfeiture and destruction.

3004. Misbranding of Gall-Klenz. U. S. v. 27 Gallons * * *. (F. D. C. No. 27779. Sample Nos. 16285-K, 42343-K.)

LABEL FILED: August 29, 1949, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about April 20, May 16, and June 18, 1949, from Des Moines, Iowa.

PRODUCT: 27 gallons of a drug, some of which had been repackaged into 288 2-ounce and 6-ounce bottles labeled "Gall-Klenz," at Detroit, Mich., in possession of the F. A. R. Chemical Co.

Examination of the product showed that it contained alcohol, sodium salicylate, phenolphthalein, bile extract, sodium oleate, menthol, and aromatics.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article, namely, a circular entitled "Dear Friend" and leaflets entitled "Valuable Knowledge Everyone Should Know," "Bowel-

Klenz," and "Directions for Taking Gall-Klenz," were false and misleading since the article would not be effective for the purposes stated and implied in the labeling; since it did not conform to all food and drug laws; since it contained drugs; since it was not harmless; and since it was capable of causing the laxative habit. The statements represented and suggested that the article conformed with all food and drug laws; that it contained no drugs; that it was a harmless non-habit-forming liquid; that it would be efficacious in the treatment of liver and gall disorders, such as gallstones, stomach and bowel distress, indigestion, and gas; that it would restore the liver to its natural healthy state; that it would stimulate a flow of pure bile; that it would restore the stomach and other dependent organs to a normal activity; that it would enable one to regain good health; and that it would be efficacious in the treatment of pains in the side, around the waist line, and in the region of the heart or appendix, gallstones, gas, colic, indigestion, belching, sourness, dyspepsia, biliousness, lack of appetite, nausea, vomiting of bile, coated tongue, duodenal ulcers, heavy distressed feeling in pit of stomach, diarrhea, piles, gas in the intestines, bloating, intestinal indigestion, pains or signs of appendicitis which often prove to be caused from gallstone or gall bladder origin, heartburn, sick, nervous, or bilious headache, bad complexion, jaundice, yellow, sallow, or greenish skin, blues and despondency, dizzy fainting spells, lack of pep, cold sweats, anemia, nervousness, high blood pressure, arthritis, diabetes, and some kidney pains.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration as are necessary for the protection of users, since the label statement "Gall-Klenz contains a laxative, and all laxatives may become habit forming" was contradicted by the statement, "Gall-Klenz is a harmless, non-habit forming * * * liquid," in one of the leaflets. The labeling did not inform the purchaser that the article if taken as directed in such labeling, namely, "The average condition * * * has shown to require from three to nine months for most lasting results" and "The treatment should be continued even after the symptoms disappear, that the disruptions caused by these disorders may be properly corrected," may result in dependence upon laxatives to move the bowels. The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: October 10, 1949. Default decree of condemnation and destruction.

3005. Misbranding of Cathartein Compound Tablets. U. S. v. 60,000 Tablets
* * *. (F. D. C. No. 27779. Sample Nos. 16281-K, 42340-K.)

LABEL FILED: August 29, 1949, Eastern District of Michigan.

ALLEGED SHIPMENT: On or about April 28, 1949, by the Standard Chemical Co., from Des Moines, Iowa.

PRODUCT: 60,000 *Cathartein Compound Tablets* at Detroit, Mich. Examination showed that the tablets contained belladonna alkaloids, phenolphthalein, cascara sagrada extract, podophyllin, aloin, and ginger oleoresin.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the conditions for which it was intended to be used.

DISPOSITION: October 11, 1949. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS**DRUGS FOR HUMAN USE***

3006. Misbranding of Nelson's Hygienic Powder. U. S. v. Great Lakes Pharmacal Corp. and Paul M. Hiller. Motion to remand case to Administrator denied. Plea of guilty on behalf of corporation; plea of not guilty by individual. Tried to the court. Fine of \$500 against corporation; case against individual dismissed. (F. D. C. No. 25625. Sample No. 41626-K.)

INFORMATION FILED: April 1, 1949, Northern District of Ohio, against the Great Lakes Pharmacal Corp., Cleveland, Ohio, and Paul M. Hiller, president of the corporation.

ALLEGED SHIPMENT: On or about March 3, 1948, from the State of Ohio into the State of Michigan.

PRODUCT: Analysis showed that the product was a white, aromatic powder containing 74% boric acid, 22.7% zinc sulfate, 0.36% phenol, 2.11% oxyquinoline sulfate, and aluminum compounds.

LABEL, IN PART: "Nelson's Hygienic Powder * * * Great Lakes Laboratories Cleveland, Ohio."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading. The statements represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of leucorrhea, vaginitis, all inflamed conditions, catarrh, all inflamed mucous membranes, wounds, ulcers, abscesses, and sores. The article would not be efficacious for such purposes.

DISPOSITION: A motion was filed on behalf of the defendants, requesting that the case be remanded to the Federal Security Administrator for review and reconsideration of the charges, on the ground that the matter was a minor violation that could be disposed of under Section 306 of the Act. This motion was heard by the court on October 11, 1949, and was overruled. A plea of guilty was entered on behalf of the corporation and a plea of not guilty was entered by the individual.

The case came on for hearing before the court on October 12, 1949, on the question of the responsibility of Mr. Hiller for the violation. At the conclusion of the testimony on such question, the court, on October 12, 1949, dismissed the case against the individual and imposed a fine of \$1,000 against the corporation. A motion for a new trial was filed on behalf of the corporate defendant but was overruled by the court; however, the fine imposed against this defendant was reduced to \$500.

3007. Misbranding of Patrick's Lung Remedy. U. S. v. Lewis Patrick. Plea of not guilty. Tried to the jury. Verdict of guilty. Defendant sentenced to serve 8 months in Federal institution. (F. D. C. No. 25589. Sample No. 14124-K.)

INFORMATION FILED: February 23, 1949, Southern District of West Virginia, against Lewis Patrick, residing at Stone, Ky., and doing business at Williamson, W. Va.

*See also No. 3004.

ALLEGED SHIPMENT: On or about May 18, 1948, from the State of West Virginia into the State of Indiana.

PRODUCT: Analysis showed that the product was a viscous, aqueous liquid with an aromatic odor and sweet taste, and that it contained chiefly sugar, with a small amount of plant extractives, including a trace of unidentified alkaloids.

LABEL, IN PART: "The Patrick's Lung Remedy Herb Compound * * * Contains: Yellow Dock, Bur Dock, Wild Cherry, Sarsaparilla, Hoarhound, Elecampane, Golden Seal, Syrup."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Patrick's Lung Remedy" and the statement "For Treatment of Weak Lung Condition," borne on the label of the article, were false and misleading. The name and statement represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of lung ailments, and in the treatment of a weak lung condition, whereas the article would not be efficacious for such purposes.

Further misbranding, Section 502 (a), certain statements in accompanying circulars entitled "Attention! Patrick's Lung Remedy" and in an undated letter beginning with the words "Dear Friend: Your order has been mailed this date" were false and misleading. The statements represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of tuberculosis, whereas the article would not be efficacious for such purposes.

DISPOSITION: A plea of not guilty having been entered, the case came on for trial before the court and jury, and at its conclusion the jury returned a verdict of guilty. On December 16, 1949, the court sentenced the defendant to serve 8 months in the Federal institution at Mill Point, W. Va.

3008. Misbranding of Se-Bex Tablets, D-E Plex Capsules, and vitamin A capsules. 1 Drum, etc. (F. D. C. No. 27792. Sample Nos. 20067-K to 20069-K, incl., 20098-K, 20099-K.)

LABEL FILED: September 1, 1949, District of Nebraska.

ALLEGED SHIPMENT: On or about August 26, 1948, and May 4 and 11, 1949, from Chicago, Ill., and Detroit, Mich.

PRODUCT: 1 drum containing 50,750 *Se-Bex Tablets*; 2 drums each containing 52,800 *D-E Plex Capsules*; 23 combination cartons labeled *A-D-E Plex Capsules*, each containing 1 100-tablet bottle of *D-E Plex Capsules* and 1 100-tablet bottle of *vitamin A capsules*; and 2 price lists entitled "Guardian Vitamins," in possession of Vitamin Industries, Inc., at Omaha, Nebr.; also 8 100-tablet bottles of *Se-Bex Tablets*; 7 combination cartons labeled *A-D-E Plex Capsules*, which were packaged in the same manner as the capsules in the 23-carton lot; 1 placard headed "Arthritis Sufferers! Famous A-D-E Plex"; and 1 placard headed "Hay Fever Sufferers. Try Se-Bex," in possession of The Vitamin Store, Omaha, Nebr.

LABEL, IN PART: (Bottle) "Tablets Se-Bex Vitamin C with B Complex"; (carton) "Guardian 200 Capsules A-D-E Plex" and "Guardian 100 Capsules D-E Plex. Each D-E Plex Capsule contains: Vitamin D 25,000 U. S. P. units * * * Vitamin B₁ 3 Mgm., Vitamin B₂ 2 Mgm., Vitamin C 37.5 Mgm., Niacinamide 20 Mgm., Calcium Pantothenate 1 Mgm., Vitamin B₆ 100 Mgm., Alpha Tocopherol 10 Mgm. * * * Each amber capsule contains: Vitamin A 5,000 U. S. P. units."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the price lists and placards accompanying the articles were false and misleading. These statements represented and suggested that the *Se-Bex Tablets* were ef-

fective in the treatment of hay fever and allergic disorders, and that the *D-E Plex Capsules* in combination with the *vitamin A capsules* were an adequate and effective treatment for arthritis, primary fibrositis, and muscular rheumatism. The articles were not effective in the treatment of the stated conditions. The articles were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: September 30, 1949. Default decree of condemnation and destruction.

3009. Misbranding of Colusa Natural Oil Capsules and Colusa Natural Oil. U. S. v. 4 Bottles, etc. (F. D. C. No. 25160. Sample Nos. 22948-K, 22949-K.)

LABEL FILED: July 9, 1948, Northern District of Alabama.

ALLEGED SHIPMENT: On or about July 6, 1948, by the Colusa Remedy Co., from Los Angeles, Calif.

PRODUCT: 4 100-capsule bottles of *Colusa Natural Oil Capsules* and 13 2-ounce bottles of *Colusa Natural Oil* at Birmingham, Ala. Analysis indicated that the oil consisted of unrefined petroleum oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading since they represented and suggested that the articles, alone or in combination, were effective in the treatment of psoriasis, eczema, poison ivy, poison oak, acne, and leg ulcers, whereas the articles were not effective for such purposes.

DISPOSITION: September 13, 1948. Default decree of condemnation and destruction.

3010. Misbranding of Nue-Ovo. U. S. v. 34 Cartons * * *. (F. D. C. No. 27182. Sample No. 50439-K.)

LABEL FILED: May 11, 1949, District of Idaho.

ALLEGED SHIPMENT: On or about March 14, 1949, by Research Laboratories, Inc., from Portland, Oreg.

PRODUCT: 34 cartons, each containing 3 1-pint bottles, of *Nue-Ovo* at Caldwell, Idaho.

LABEL, IN PART: (Bottle) "Nue-Ovo * * * Ingredients: An aqueous extraction of Plume Thistle, Burdock, Quassia, Sage, Cinnamon, Horehound, Ginseng, Calamus, Dandelion, Althea, Kola Nut, Sodium Salicylate, Cascara, Licorice, Vitamin B₁"; (shipping case) "Nue-Ovo for Rheumatism and Arthritis."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Nue-Ovo for Rheumatism and Arthritis," which appeared on the shipping case label, was false and misleading since the article was not effective in the treatment of rheumatism and arthritis.

DISPOSITION: June 13, 1949. Default decree of forfeiture and destruction.

3011. Misbranding of Kimko. U. S. v. 90 Bottles, etc. (F. D. C. No. 27772. Sample Nos. 62055-K, 62056-K.)

LABEL FILED: August 18, 1949, Eastern District of Arkansas.

ALLEGED SHIPMENT: On or about May 3, 1949, by the Kimko Co., from Denver, Colo.

PRODUCT: 90 12-ounce bottles and 450 6-ounce bottles of *Kimko* at Paragould, Ark., together with a number of leaflets and booklets entitled "What Users

Of Kimko Have Found Out," a number of leaflets and counter display cards entitled "For Aches and Pains," and a number of small cards entitled "For That Nagging Back-Ache." Examination showed that the product consisted of isopropyl alcohol, water, camphor, and material extracted from gall.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the article were false and misleading since the article would not be adequate and effective in the treatment of the conditions represented and suggested. The statements represented and suggested that the article was an adequate and an effective treatment for spains, bruises, backache, sore, painful, swollen, or weak joints, bronchitis, arthritis, varicose veins, headache, rheumatism, leg cramps, puncture wounds, bee stings, tonsillitis, sore throat, indigestion, numb fingers, enlarged glands, wheezing respiration, paralysis following a stroke, head colds, abdominal pain, toothache, pleurisy, stiffness and pain in the neck, tumors of the extremities, earache, skin rashes, and swollen limbs.

Further misbranding, Section 502 (a), the statements on the bottle label "Active Ingredients Alcohol * * * Alcohol 53¾ percent by Vol." were false and misleading since the article did not contain ethyl alcohol but contained isopropyl alcohol.

DISPOSITION: October 27, 1949. The Kimko Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, and for destruction of the original bottle labels, and the leaflets, booklets, counter cards, and small cards, under the supervision of the Federal Security Agency.

3012. Misbranding of D-O-D. U. S. v. 7 Cans, etc. (F. D. C. No. 27832. Sample No. 51885-K.)

LABEL FILED: September 9, 1949, Southern District of Ohio; amended label filed October 10, 1949.

ALLEGED SHIPMENT: On or about May 20, 1949, by the C. Nelson Smith Co., from West Allis, Wis.

PRODUCT: 7 4½-ounce cans and 1 1-pound can of *D-O-D* at Columbus, Ohio, together with a number of pamphlets entitled "*D-O-D* The Human Cleanser" received by the consignee from the company sometime in 1948. Examination showed that the product consisted of sodium bicarbonate and potassium permanganate, with small proportions of magnesium sulfate and charcoal.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the pamphlets were false and misleading since the article was not effective in the treatment of the conditions, or for the purposes, stated and implied. The statements represented and suggested that the article was effective in the treatment of gangrene, diabetic gangrene, diarrhea, fistula, kidney and bladder trouble, tuberculosis of the kidney, eczema, running sores, shingles, hives, rashes, barber's itch, asthma, influenza, bronchitis, catarrh, colds, sore throat, hay fever, grippe, foot troubles, poisonous bites, flesh infection, blood poisoning, carbuncles, boils, stomach trouble, dyspepsia, dysentery, ptomaine poisoning, pyorrhea, diabetes, and stomach ulcers; that the article would rid the system of injurious substances; that it would prevent the entrance of infections through the mouth; and that when used as a douche it would maintain good health of womanhood.

DISPOSITION: December 1, 1949. Default decree of destruction.

3013. Misbranding of Lin-Ox-Ol. U. S. v. 54 Cartons, etc. (F. D. C. No. 27920. Sample No. 44878-K.)

LIBEL FILED: October 18, 1949, District of Minnesota.

ALLEGED SHIPMENT: On or about August 8, 1949, by the Lin-Ox-Ol Sales Corp., from Fargo, N. Dak.

PRODUCT: 54 cartons each containing a leaflet entitled "At Home or Away" and 1 3-ounce bottle of *Lin-Ox-Ol* at Minneapolis, Minn. Examination showed that the product consisted essentially of oil of turpentine, a nonvolatile oil, such as linseed oil, and camphor, with traces of sulfuric acid and potassium nitrate.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following labeling statements were false and misleading since the article was not effective in the treatment of the conditions represented and suggested: (Carton and bottle labels) "Relieves Pain * * * Bruises, Sores * * * Boils, Carbuncles * * * Itch, Eczema, Acne * * * Chest Colds, Sore Throat * * *" and (leaflet) "* * * Lin-Ox-Ol, however, softens the tissue and aids nature in restoring it to a healthy, normal condition * * * Bruises, sprains * * * Boils, Carbuncles * * * For eczema, itch, ringworm, psoriasis, pimples, acne, and other externally caused skin conditions * * * Varicose Veins * * * Chest Colds, Sore Throat."

DISPOSITION: December 21, 1949. Default decree of destruction.

3014. Misbranding of Vegex Extract. U. S. v. 184 Jars, etc. (F. D. C. No. 28017. Sample No. 42371-K.)

LIBEL FILED: October 14, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: By the Vegex Co., from New York or Peekskill, N. Y. The product was shipped on or about March 28, April 26, June 8, July 15, and September 7, 1949, and a number of circulars were shipped on or about July 15, 1949.

PRODUCT: 184 8-ounce jars, 222 4-ounce jars, 62 1-pound jars, and 3 10-pound tins of *Vegex Extract* at Chicago, Ill., together with a number of circulars entitled "Vegex Yeast-Vegetable Extract."

LABEL, IN PART: (Jar and tin) "Vegex Extract Meaty Flavor Meat Free Supplies Vitamin B Complex & Iron * * * Yeast Vegetable Extract with Added Salt and Iron."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars were false and misleading. The statements represented and suggested that the article was effective in the treatment and cure of diabetes, whereas the article was not effective for such purposes.

DISPOSITION: January 11, 1950, The Vegex Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond on condition that the circulars be destroyed and that the product be sold in the usual course of business, in conformity with the law.

3015. Misbranding of Amberin. U. S. v. 8 Cartons * * *. (F. D. C. No. 27447. Sample No. 40866-K.)

LIBEL FILED: July 6, 1949, Western District of Washington.

ALLEGED SHIPMENT: On or about April 20, 1949, by the Stanley Drug Products Co., from Portland, Oreg.

PRODUCT: 8 cartons, each containing 6 dozen 4-ounce bottles, of *Amberin* at Seattle, Wash. Examination showed that the product consisted essentially of acetone 84 percent, volatile oils, including wormwood oil, menthol and thymol 9.2 percent and water.

LABEL, IN PART: "Amberin * * * Distributed Solely by The Amberin Company, Walla Walla, Washington."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling were false and misleading since they represented and suggested that the article would be effective for the treatment and cure of hemorrhoids, whereas it would not be effective for that purpose: (Carton) "Hemorrhoids" and (bottle label) "Hemorrhoids * * * Directions * * * Apply Amberin to a folded pad and affix to outside area, covering rectum * * * If region is highly irritated or bleeding, you may experience a burning sensation which passes quickly. External or protruding types react much quicker to Amberin than other types. Amberin is ineffective in some types of itching piles, but may give relief when basic cause is not allergy."

DISPOSITION: December 1, 1949. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

3016. Misbranding of eucalyptus compound and inhalers. U. S. v. 936 Bottles, etc. (F. D. C. No. 28246. Sample Nos. 71977-K to 71979-K, incl.)

LABEL FILED: November 10, 1949, Northern District of Ohio.

ALLEGED SHIPMENT: On or about August 25, September 1, and October 5 and 21, 1949, from New York to Columbus, Ohio, and on or about October 21 and 26, 1949, from Columbus to Cleveland, Ohio.

PRODUCT: 936 1-ounce bottles and 96 4-ounce bottles of *eucalyptus compound* and 864 *inhalers* at Cleveland, Ohio, in the possession of the Sandy Sales Co., together with a number of coupons relating to the articles. Examination showed that the *eucalyptus compound* consisted essentially of volatile oils, including eucalyptus oil, menthol, and camphor, and that the *inhaler* consisted of a glass tube tapered at one end and containing a plug of cotton between two perforated corks.

LABEL, IN PART: "Miracle-Brand Eucalyptus Compound * * * Distributed by Sandy Sales Co. * * * Cleveland 20, Ohio" and "Miracle-Brand Eucalyptus Compound Combination Inhaler."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the coupons were false and misleading since the articles were not effective in the treatment of the conditions stated and implied. The statements represented and suggested that the articles would be effective in the treatment of sinus, head colds, neuritis, lumbago, lung trouble, T. b., croup, arthritis, sore throat, pneumonia, rheumatism, asthma, gland trouble, bronchitis, fever, ulcers, ear trouble, and infections of the throat. The articles were misbranded while held for sale in Columbus, Ohio, after shipment in interstate commerce.

DISPOSITION: January 4, 1950. Default decree of condemnation and destruction.

3017. Misbranding of Tox Eliminator devices. U. S. v. 1 Device, etc. (and 1 other seizure action). Tried to the court. Judgment for claimant; judgment reversed upon appeal. Decree of condemnation. (F. D. C. Nos. 16687, 17659. Sample Nos. 25466-H, 26665-H.)

LIBELS FILED: July 12 and October 15, 1945, District of Colorado and District of Utah.

ALLEGED SHIPMENT: One of the devices and various circulars were shipped on or about April 2, 1945, by Tox Eliminator Co., Inc., from Los Angeles, Calif., to Denver, Colo., and the other device and various circulars were shipped on or about May 25, 1945, by Glen Albright, agent for the Tox Eliminator Co., Inc., from Denver, Colo., to Price, Utah.

PRODUCT: 2 *Tox Eliminator devices*,¹ at Denver, Colo., and 1 at Price, Utah, together with a number of accompanying circulars entitled "The Modern Scientific Drugless Way to Health" and "The Magic Power of Water."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label designation "Tox Eliminator" and the words "Tox Eliminator" and "Tox Elimination" appearing in the circulars were false and misleading since they represented and suggested that by use of the article any toxins in the body would be eliminated, whereas such was not the case.

Further misbranding, Section 502 (a), certain statements in the circulars were false and misleading since the article would not fulfill the promises of benefit stated and implied by such statements.

The false and misleading statements are set forth in the court opinion below.

DISPOSITION: J. O. Wolvin, trading as the Tox Eliminator Co., Inc., appeared as claimant and filed answers denying that the devices were misbranded. Thereafter, the libel actions were consolidated for trial in the District of Utah. The trial commenced on January 17, 1946, before the court without a jury. On January 21, 1946, after consideration of the evidence and arguments of counsel, the court handed down its findings of fact and conclusion of law, the nature of which are set forth in the court opinion below; and on the basis thereof, the court entered a decree in favor of the claimant. Upon denial of the government's motion for a new trial, an appeal was taken to the United States Circuit Court of Appeals for the Tenth Circuit, and on February 27, 1947, the following opinion was handed down by that court:

HUXMAN, Circuit Judge: "The government has appealed from the judgment of the United States District Court for the District of Utah denying its prayer for the seizure and condemnation of two certain devices, each bearing a plate reading 'Tox-Eliminator Tox Eliminator Co. Inc. Glendale, Calif. Ser. No. 513' and for the seizure of certain circulars which accompanied the devices. The devices are identical, differing only as to the number of the name plate attached thereto. The action was instituted under the Federal Food and Drug Act, 21 USCA 301 et seq.¹ Trial was to the court, and judgment was entered dismissing the libel.

¹ The applicable statutes are as follows: 321 "(h) The term 'device' * * * means instruments, apparatus, and contrivances, including their components, parts and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals."

321 "(m) The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

"Sec. 352. Misbranded drugs and devices.

"A drug or device shall be deemed to be misbranded * * *.

"False or misleading label—

"(a) If its labeling is false or misleading in any particular."

"The parties stipulated that the sale of the two devices in question had been made, one to a doctor of naturopathy and the other to a doctor of chiropractic, and that the devices were displayed in the places of business of these two men for the purpose of selling the service of the devices, and that the devices were displayed together with certain circulars extolling their merits, and that both the device and the circulars had been transported in interstate commerce.

"The device is described as a colonic irrigator. It differs from the ordinary enema device in that it has an inflow and an outflow tube. The inflow tube is equipped with a thermostatic valve by which the temperature of the water can be regulated, and a pressure valve which limits the pressure of the water entering the body to forty inches. The outflow tube has a transparent arrangement by which the contents coming from the bowels can be seen and observed as they leave the body. One of the circulars involved was labeled 'The Modern Scientific Drugless Way to Health,' and the other was called 'The Magic Power of Water.'² The device is attached to an ordinary water faucet while in use,

² These two circulars in part read as follows:

"The Magic Power of Water.

"From 58 to 65 per cent of the human body is water.

"The bones have only 22 per cent, but the liver contains 69 per cent, muscles 75 per cent, and the kidneys as much as 82 per cent.

"The inside of the cells is fluid and consists largely of a solution of various substances in water. Bodily activity depends on aqueous solutions. Water is used to flush away the waste products of cell activity.

"Water furnishes a medium for digestion, absorption, metabolism (chemical change within the body in nutrition and secretion), and excretion. All these processes, chemical or physical, can take place only in the presence of water. Water is the vehicle for transportation of food, waste, hormones (internal secretions), gases, etc.

"Water is taken into the body not only with our drink but with nearly all foods; fresh meat and vegetables average about 75 per cent of water. It is absorbed mainly from the small intestine.

"By means of the lungs, skin and kidneys we eliminate water. There is a tube, leading out of each kidney, down which there runs a continual trickle of water, carrying dissolved in it the waste substances which have been separated from the blood.

"Air contains oxygen which enters the blood stream through the lungs and revitalizes it. A pure blood stream is a prime essential to health. By means of water and air poisonous waste matter is eliminated through the bowels, kidneys, lungs, skin and liver.

"Tox Elimination is a new method of treatment for disturbed bowel conditions using Nature's agencies, water and air. It is astonishingly effective in a wide variety of cases where all other treatments have failed. Come and see for yourself what Nature's magic powers, properly employed can do for you. If the examination shows your case to be one which requires the services of the Tox Eliminator, a demonstration treatment will be given. If you are not entirely convinced, there will be no charge. . . .

"10 Points of Tox Elimination.

"This natural and drugless therapy assists in accomplishing the following:

"1. Cleansing the colon, thoroughly and in a harmless manner.

"2. Massaging the bowel and helping give necessary tone to tissues involved.

"3. Helps to purify the blood stream; proved by microscopic examination after treatments.

"4. Assists in relieving rheumatic, arthritic and neuritic pain.

"5. Helps reduce hypertension or high blood pressure, thus easing the work of the heart and freeing its cells, and the brain, from undue strain.

"6. Helps to lessen the extra burden which is thrown on the liver and kidneys by improper elimination.

"7. Assists and improves sinus and antrum complications.

"8. Helps in re-establishing a normal peristalsis or natural muscular activity of the intestines.

"9. Helps improve the complexion, by assisting in eliminating the causes of pollution of the blood stream.

"10. Helps in preventing the hardening of the arteries, by minimizing the deposits of calcium and magnesium salts on arterial wall. . . .

"Tox Elimination is a remarkable new treatment that cannot be compared with any other. I firmly believe this instrument will enable me to more thoroughly cleanse the colon of disease-producing waste than is possible by any other method.

and uses water coming from water mains. Much of the controversy centers around the representations contained in these two circulars.

"A pulsating stream of water and air bubbles is introduced into the bowel in a scientifically controlled manner. This pulsating stream penetrates readily into the impacted colon, hitherto inaccessible to most any other method of treatment. A sluggish or diseased colon is a contributing cause of most ailments.

"The air, oxygen and water loosen and dissolve the coats of mucus and stale and encrusted fecal matter that adheres to the walls of the large bowel—in many instances causing it to become distended or ballooned.

"When the liver, colon and kidneys are not in perfect order they cannot do their work properly and as a result toxins are not properly discharged and are carried by the blood to every part of the body, tissues, joints, sinus, appendix, gall bladder and so on.

"Drugless methods, by removing the disease-producing materials at their foundation head, helps the body to stop further damage and rebuild the affected parts and restore them to normal. Causes of irritation and numerous infections are removed. . . .

"The Modern, Scientific, Drugless Way to Health.

"My policy of keeping abreast of latest developments and providing my patients with the very best science has to offer in the treatment and relief of disease has made it necessary for me to adopt a remarkable new instrument to assist in getting at the very bottom and basic cause of a large number of ailments that have heretofore resisted the very best efforts of all branches of healing.

"When the colon is not functioning properly, the small intestine, stomach and the entire digestive tract are sure to be affected.

"I believe this new instrument, the Tox Eliminator will enable me to more thoroughly cleanse the colon than is possible by any other method ever before conceived. The bowels are part of Nature's medium for eliminating poisons from the system. When these poisons have been removed, the blood stream becomes purified and performs its marvelous function of healing and correcting in all parts of the body.

"I investigated this instrument thoroughly before installing it, and in all my years of practice have never before been so impressed by any method of treatment. The results are positively astonishing. If you have tried everything else without relief, you have a surprise in store for you. You really can benefit greatly and not only feel the improvement at once but can actually see with your own eyes the positive evidence of what is causing your trouble. . . .

"Let me impress you with some great truths. Curing is done by the blood stream. Medicines and treatments are effective only when they cause the system to purify the blood stream. Most ailments arise through toxins being thrown into the blood stream and a large share of this comes from the bowels.

"Polluted blood that helped cause an ailment, obviously cannot cure it.

"The bowels are one of Nature's chief agencies for purifying the blood stream. Hence, a thorough cleansing of the colon is helpful toward regaining health.

"And here is the most important of all. . . .

"A thorough cleansing of the colon is not possible through any other means than Tox Elimination. Laxatives often inflame the bowel walls and leave a coating of infectious matter. Enemas and many types of colonic treatment often only partially cleanse the bowel. A daily bowel movement means absolutely nothing as to the condition of the intestinal tract.

"The following are some of the ailments almost invariably accompanied by intestinal toxemia and which respond to Tox Elimination plus such other treatment as your condition requires:

"Arthritis, rheumatism, neuritis, high and low blood pressure, toxic heart conditions, ulcers of stomach and bowels, colitis, chronic appendicitis, gall bladder and liver troubles, kidney and bladder troubles, asthma, migraine, toxic skin troubles, lumbago, and a host of ills that have heretofore been obscure.

"Improper function of the colon is the most frequent contributing cause of intestinal toxemia and the following accompanying symptoms and ailments. They can now be successfully treated by our methods.

"Arthritis, Asthma, Colitis, Constipation, Excessive Fatigue, Foul Breath, Headache, Gall Bladder complications.

"High and Low Blood Pressure, Indigestion, Irregular Heart, Kidney and Bladder Complications, Liver Complications, Lumbago, Menopause Disturbances, Muddy or Pimply Complexion, Migraine.

"Nervousness, Pruritus Ani, Rheumatism, Sinus Trouble, Run Down Condition, Shortness of Breath, Sleeplessness, Ulcers of Colon."

"The government's case was based upon the testimony of five medical experts whose qualifications in their respective fields stand admitted. They testified that while they had never used the device or had never seen it in use, they understood fully the principles upon which it operated, namely, the washing out of the colon by forcing a stream of pulsating water into the intestines. They explained in considerable detail the physiology of the human system, as well as the causes of many of the diseases listed in the circulars, and the treatments therefor where known. They admitted that the causes of a number of the diseases of the body listed in these circulars were still unknown, and that the treatment therefor was not definitely catalogued. They testified that intestinal toxemia, referred to in the circular, was not a condition known to medical science. While admitting that the fecal matter in the colon contained some toxin, they testified that toxins are not absorbed in any considerable quantity into the blood stream from the colon. They denied emphatically that washing out the colon would purify the blood stream. They testified further that such toxins as entered the blood stream from the colon went first to the liver where they were rendered harmless. They testified that the function of the colon had very little, if anything, to do with the numerous diseases mentioned in the circular. They also testified that a colonic irrigation would not cure hardening of the arteries, migraine, lumbago colitis, gall bladder complications, high or low blood pressure, irregular heart, rheumatism, or any of the other named diseases. They testified that enemas or colonic irrigations are helpful in a limited sense only to relieve temporary discomfort caused by severe impaction, or as a preparation in case of some major abdominal surgical operations, but that colonic irrigations do not and cannot constitute an appropriate treatment for any of the diseases listed in the circulars.

"The defense, on the other hand, offered the testimony of Dr. Neal Bishop, a doctor of chiropractic, and of J. O. Wolvin, a layman who was the manufacturer and distributor of the device in question. Dr. Bishop testified that the statements in the circulars were true; that he had treated patients with the device in connection with other therapy, such as chiropractic adjustments, diathermy and others, and that its use was helpful. He did not testify specifically that its use had effected a cure in a single case of any of the diseases enumerated in the circulars. Certain X-rays which he had taken of patients before and after using the device were introduced to show, according to his contention, improved conditions in the posture and texture of the colon. Wolvin testified that the use of the device had cured him of a chronic case of asthma, and that when the asthma had a tendency to recur, his use of the device eliminated it. The only other evidence offered by the defense consisted of excerpts from several medical books, only one of which stated that colonic irrigation would aid in the treatment of any of the diseases named in the circular, other than some diseases of the colon. This in substance is the testimony upon which the judgment appealed from is based.

"The excerpts from these medical books were introduced by the defense over the objection of the government. The court made the following findings of fact and conclusions of law:

FINDINGS OF FACT

"(1) That the libellant has not offered any substantial evidence upon which to entitle it to judgment as prayed.

"(2) That the plate affixed to the colonic irrigator described in each of the labels of information and bearing the serial number and the words 'Tox-Eliminator-Tox-Eliminator Co.' does not constitute misbranding or mislabeling as set out in said Libels, or otherwise.

"(3) That the literature offered and received herein as exhibits 1, 2, 3, and 4, and by this reference made a part hereof, constitutes labeling as such word is defined under Section 321 (m), Title 21 of the USCA.

CONCLUSION OF LAW

"As conclusion of law from the foregoing facts the court finds that the relief prayed for by the libellant in these proceedings should be and is denied. . . .

"In general, the assignments of error present two issues which may be summarized as follows: First, the court erred in admitting in evidence excerpts from the medical treatises offered by the defendants. Second, the court's

findings of fact are contrary to the clear weight of the evidence, and therefore erroneous.

"While the authorities are not in complete accord, the weight of authority is that medical books and treatises are not admissible to prove the statements therein contained.³ The trial court erred in admitting and receiving in evidence excerpts from these books offered by the defendants for the purpose of establishing the truth of the statements contained therein.

"While the trial court did not exclude the testimony of the five medical experts offered by the government, it was of the apparent opinion that their testimony was entitled to no consideration because they had neither tested the device in question nor had they observed it in operation. The court stated: '... my impression is that the government cannot come in here and rely upon the bald opinion of anybody who has never experimented with the thing in question. ... So I am inclined to hold in this case that the government has failed to produce substantial proof of its charges ... based upon, as I view it, reliance solely upon the opinion of the medical men.' In other words, the court refused to consider the testimony of the medical experts because he did not consider them qualified to testify concerning this device. Only in this way could the court have made Finding No. 1, 'That the libellant has not offered any substantial evidence upon which to entitle it to judgment as prayed.'

"That these medical experts were competent and qualified to testify as to matters in issue is clear. They were not disqualified merely because they had not used the device in question or had not seen it in operation. They testified not only that they were conversant with colonic irrigation, but also that they were familiar with the principles of the particular device in question. In its fundamentals, this device is not essentially different from any other circulatory apparatus for the purpose of giving an enema. The main function of all such devices is to introduce a flow of water into the colon for the purpose of cleansing it of accumulated waste matter. The fact that this device has a thermostatic control, a pressure valve, and may be attached to a faucet or may force the water further into the colon, in no wise changes its essential or general functions. Being fully conversant with the principles of colonic irrigation and with the principles upon which this device operated, the testimony of these medical experts was competent⁴ and constituted substantial evidence.

"Ordinarily an ultimate finding of fact by a trial court is binding upon the appellate court if sustained by the record, but if the finding is clearly erroneous or is based upon a misapplication of law to evidentiary findings, it is not binding upon the appellate court.⁵

"The trial court's Finding No. 1. 'That the libellant has not offered any substantial evidence upon which to entitle it to judgment as prayed,' is clearly erroneous and must therefore be set aside.

"The court's finding that the plate attached to the device and bearing the words 'Tox Eliminator-Tox Eliminator Co., Inc., Glendale, Calif. Ser. No. 513' does not constitute misbranding or mislabeling, finds support in the record when such label is considered separate and apart from the circulars in question. There is evidence that a colonic irrigation does eliminate some toxins from the colon. Under such testimony, a machine called a tox eliminator which tends to remove some toxins is not misbranded. The court found that the two circulars in question constituted labeling as defined in the Act. It did not, however, make a separate finding whether the statements contained therein were true or constituted mislabeling. It must, however, have been of the opinion that it did not constitute mislabeling, otherwise it could not have concluded as a matter of law that the relief prayed for should not be granted.

"In order for the government to prevail, it was not necessary to prove that all the representations in the two circulars were false. The charge of mislabeling

³ U. P. Ry. Co. v. Yates, 79 F. 584; Miss. Power & Light Co. v. Whitescarver, 68 F. 2d 928; U. S. v. 50¾ Doz. Bottles, Sulfa-Seb. 54 F. Supp. 759; Annotations 65 ALR 1102; 20 Am. Jur., Evidence, Sec. 968; 32 C. J. S., Evidence, Sec. 718.

⁴ Irwin v. Federal Trade Comm., 143 F. 2d 316; U. S. v. 11¼ Doz. Packages, etc., 40 F. Supp. 208.

⁵ U. S. v. Armature Rewinding Co., 124 F. 2d 589; Bratt v. Western Air Lines, 155 F. 2d 850; Sears, Roebuck & Co. v. Talge, 140 F. 2d 395; Bailey v. Smith, 14 F. 2d 519.

would be established if the evidence proved any one of the representations to be false.⁶ Here the substantial evidence by the government establishes the falsity, with minor exceptions, of practically every one of the broad claims set up in these circulars. The defendants offered positive evidence only as to one claim—asthma. One witness testified that the tox eliminator cured his asthma. No attempt was made to refute or contradict the government's evidence as to each of the other claims. The mere statement by Dr. Bishop that he had obtained good results from use of the device does not overcome the positive evidence of the medical experts. It must therefore be conceded that the government has established the falsity of many of these claims not only by the greater weight of evidence but also by all the evidence in the record. The finding of the trial court accordingly should have been that the two circulars in question constituted mislabeling.

"The objection is not to the use of this device or that it does not have a useful place in the art of healing. The vice is in the way and manner in which it is represented and the claims which are made for it in these circulars, which under the stipulation of facts and findings of the court constitute a part of the labeling of the device. For the purpose of this opinion, it may be conceded that its use in flushing out the colon under expert supervision has a tendency to eliminate some toxins therefrom, thus preventing their entrance into the blood stream and thereby contributing somewhat to the purification of the blood and thus, in the ultimate, contributing to some extent to improvement in general health. But this is not what the labeling circulars state. In effect, they hold the machine out as a cure-all for all the ills that affect the human body. The authors of this literature apparently borrowed a leaf from the book of the ancients, who wanted to appease all the gods by erecting a statue to them and who, when they had erected a statue to all of the known gods, then, fearing that they might have overlooked one, erected another statue to the unknown god. Thus, the authors of 'The Modern, Scientific Way to Health,' after naming all the known ills of the body and representing that they would respond to the use of the tox eliminator, added this phrase, 'and a host of ills that have heretofore been obscure.' Nothing is overlooked. Relief is promised from every ill, whether known or unknown.

"It may be argued that the circulars do not promise a full cure in all of these cases, but only relief and improvement. But, as stated by the Supreme Court, 'Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity as well as from statements which are false. It is not difficult to choose statements, designs and devices which will not deceive. Those which are ambiguous and liable to mislead should be read favorably to the accomplishment of the purpose of the Act.'"

"A casual reading of the circulars is sufficient to establish beyond doubt that the statements in these circulars would induce and were intended to induce the belief in the minds of many of the ailing and suffering that the tox eliminator promised absolute and general relief from all their ailments. The circulars are inherently dishonest and deceiving and constitute misbranding within the meaning of the Act. The government established its case by substantial and preponderant evidence and is entitled to prevail. It follows that Finding No. 1 has no support in the record and must be set aside. This finding of the trial court is therefore set aside, and the judgments are severally REVERSED, and the causes are remanded with directions to proceed in conformity with the views expressed herein."

Pursuant to the foregoing opinion, the matter came on for hearing before the United States District Court for the District of Utah, upon motion of the Government for summary judgment. No appearance was made on behalf of the claimant, and, accordingly, on October 9, 1947, judgment of condemnation was entered. The court ordered that the devices and circulars be destroyed, unless the claimant should bring the two devices into compliance with the law

⁶ Goodwin v. U. S., 2 F. 2d 200.

⁷ U. S. v. 95 Barrels of Vinegar, 265 U. S. 438.

within a period of 60 days. One of the devices was destroyed on February 23, 1948, and the other device was destroyed on May 20, 1948.

3018. Misbranding of Pur-Ar-Lite Air Purifiers. U. S. v. 71 Devices * * *.
Tried to the court. Verdict for Government. Decree of condemnation.
(F. D. C. No. 27260. Sample No. 55219-K.)

LIBEL FILED: June 1, 1949, District of Kansas.

ALLEGED SHIPMENT: On or about March 8, 1949, by the Circlite Corp. from Chicago, Ill.

PRODUCT: 71 *Pur-Ar-Lite Air Purifiers* at Kansas City, Kans. Examination showed that the device consisted of a Sylvania 4W No. S1119 bulb, together with the necessary electrical connections.

LABEL, IN PART: "The Pur-Ar-Lite Air Purifier."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements, which appeared in accompanying leaflets entitled "Look" and "Here It Is," were false and misleading since the device was not effective in the prevention of the diseases and conditions stated and implied: (In leaflet entitled "Look") "Pur-Ar-Lite * * * protects your family, your home from deadly air-borne bacteria * * * Guards Your Family Against Disease! Yes! Pur-Ar-Lite Air Purifier's powerful concentrated ultra-violet rays quickly, instantly deal a death blow to menacing air-borne germs which spread colds, sore throats, flu, pneumonia, measles, scarlet fever, diphtheria, smallpox and other dread contagious diseases! Pur-Ar-Lite Air Purifier is a modern scientific method of insuring your family's health! * * * In the Bedroom * * * helps protect you and your child against colds, dangerous diseases, cuts down on doctor bills!" and (in leaflet entitled "Here It Is") "In The Bedroom * * * helps protect children and adults from colds, dangerous diseases, cuts down on doctor bills!"

DISPOSITION: The Circlite Corp. appeared as claimant and filed an answer denying that the devices were misbranded. On November 2, 1949, the case came on for trial before the court without a jury, and at the conclusion of the testimony the court made the following findings of fact and conclusions of law in favor of the Government:

HILL, *District Judge:*

FINDINGS OF FACT

"(1) The Claimant, Circlite Corporation, of Chicago, Illinois, shipped in interstate commerce from Chicago, Illinois, to Kansas City, Kansas, the articles of device seized in the action:

"(2) Said devices were labeled in part 'Pur-Ar-Lite Air Purifier,' and each consisted of a 4-watt mercury arc lamp together with its associated starting and operating components mounted in a metal housing and arranged such that the radiant flux from the lamp was reflected through an opening at one end of the housing. The lamp emitted ultraviolet radiation and on testing the measured density was found to be 44.2 microwatts per square centimeter at 6 inches from the opening and 12.4 microwatts per square centimeter at 12 inches from the opening.

"(3) The labeling which accompanied the devices represented among other things that the use of one of the devices would be effective in killing air-borne bacteria and would be effective in preventing colds, sore throats, flu, pneumonia, measles, scarlet fever, diphtheria, smallpox and other contagious diseases, and would protect one's family and cut down on doctor bills.

"(4) In an average size room the number of air-borne bacteria that the device might kill would be insignificant. The ultraviolet radiation from one of the devices would have no effect in preventing the specific disease conditions for

which it was recommended or any other contagious diseases, and the use of one of the devices would not protect one's family against any disease and would not cut down on doctor bills.

"(5) The labeling of the 'Pur-Ar-Lite Air Purifier' devices involved in this action is false and misleading.

CONCLUSIONS OF LAW

"(1) This Court has jurisdiction of the subject matter in the above-entitled action.

"(2) The devices seized in this action are misbranded within the provisions of 21 U.S.C. 352(a) because the labeling of said devices is false and misleading.

"(3) The devices are condemned under the provisions of 21 U.S.C. 334."

On November 17, 1949, judgment of condemnation was entered and the court ordered that two of the devices be delivered to the Food and Drug Administration and that the remaining devices be released to the claimant under bond for relabeling under the supervision of the Federal Security Agency.

3019. Misbranding of Theraplate (device). U. S. v. 202 Devices, etc. (F. D. C. No. 27789. Sample No. 1675-K.)

LIBEL FILED: September 15, 1949, Eastern District of South Carolina.

ALLEGED SHIPMENT: The devices were shipped from New York, N. Y., on or about March 14 and April 1, 1949, by the Infra-Appliances Corp. (American Metal Industries, New York, N. Y., consignor), and quantities of printed matter were shipped from New York, N. Y., between March and May, 1949, by the Infra-Appliances Corp.

PRODUCT: 202 *Theraplate devices* at Columbia, S. C., together with a number of leaflets entitled "Theraplate Instructions," "Information Bulletin #1," and "Introducing the Theraplate," and a number of display cards entitled "It's Theraplate." The device consisted of an electrically heated resistance wire embedded in a glass plate mounted on a metal base.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling accompanying the device were false and misleading since the statements represented and suggested that the device was effective in the treatment of the conditions stated and implied, whereas it was not effective for such purposes: (In leaflet entitled "Theraplate Instructions") "Many who suffer from Rheumatism, Arthritis, Sinus and the common cold have found welcome relief from pain and discomfort in Theraplate's infrared rays * * * For Relief of Rheumatic and Arthritic Conditions * * * For Treatment of Sinus, Common Colds," (in display card entitled "It's Theraplate") "Helps relieve painful discomforts caused by Rheumatism, Arthritis, Sinusitis, common colds," (in leaflet entitled "Information Bulletin #1") "Theraplate can be successfully used in bringing about relief from such ailments as Arthritis, Rheumatism, Phlebitis, Sinus, Hay Fever, and from general aches and pains * * * Theraplate will write a spectacular history in the bringing of much needed relief to the sufferers from Arthritis, Rheumatism, Sinus, Phlebitis, Hay Fever, and other muscular aches and pains," and (in leaflet entitled "Introducing the Theraplate") "Sufferers from Arthritis, Sinusitis, Phlebitis, Hay Fever, Rheumatic and other pains have found relief by use of the Theraplate * * * Sprained ankles, Charley horses, strained ligaments, bumps and bruises are all benefited by the magic penetrating infrared rays of the Theraplate."

DISPOSITION: February 22, 1950. The Central Radiant Glass Heating Co., Columbia, S. C., claimant, having consented to the entry of a decree, judgment

of condemnation was entered and the court ordered that the devices be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

3020. Misbranding of Fowlton, D.R.D. Concentrate, Flushem, and Getsem Poultry Wormer. U. S. v. 6 Cases, etc. (F. D. C. No. 27557. Sample Nos. 64120-K to 64123-K, incl.)

LIBEL FILED: July 12, 1949, District of Minnesota.

ALLEGED SHIPMENT: On or about March 16, 17, and 23, and May 5, 10, and 31, 1949, by Dr. Jespersen's Laboratories, from Spencer, Iowa.

PRODUCT: 6 cases, each containing 4 1-gallon bottles; 9 cases, each containing 6 ½-gallon bottles; and 2 cases, each containing 12 1-quart bottles, of *Fowlton*; 4 cases, each containing 6 ½-gallon bottles; 1 case containing 5 ½-gallon bottles; 1 case containing 20 1-quart bottles; and 1 case containing 22 1-pint bottles of *D.R.D. Concentrate*; 3 cases, each containing 12 1-pound jars; 1 case containing 6 3-pound jars; and 1 case containing 5 3-pound jars, of *Flushem*; and 1 case containing 12 1-pint bottles; 1 case containing 11 1-pint bottles; and 1 case containing 116 ½-pint bottles, of *Getsem Poultry Wormer* at Buffalo, Minn., together with a number of booklets entitled "Dr. Jespersen's Poultry Guide" and a number of invoices issued by Dr. Jespersen's Laboratories, which bore therapeutic representations with respect to the products.

LABEL, IN PART: "Fowlton * * * Ingredients: Ferric Chloride, Manganese Sulphate, Potassium Dichromate, Potassium Iodide and Water"; "D.R.D. Concentrate * * * Active Ingredients: Mercuric Chloride (16.4 grs. fl. oz.) Inert Ingredients: Sodium, Calcium and Zinc Phenolsulphonates, Manganese Sulphate, Certified Color and water 96.6%"; "Flushem * * * Active Ingredients: Magnesium Sulphate (Epsom Salts), Sodium Sulphate, Sodium Bicarbonate, 95%. Inert as a laxative—Sodium Thiosulphate and Gentian Violet 5%"; and "Getsem Poultry Wormer * * * Contents: Arecoline Hydrobromide, Iron Chloride Solution, Solution Nicotine Sulphate, Copper Sulphate (22.5 grains per oz.), and Manganese Sulphate. Active Ingredients: 27½% Water 72½%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the invoices and in the booklets were false and misleading since the articles would not be effective for the purposes claimed. The false and misleading claims in the labeling represented and suggested:

That the *Fowlton* had some specific value in the treatment of disease conditions of poultry and as a tonic;

That the *D.R.D. Concentrate* had some specific value in the treatment of coccidiosis, roup, pox, and colds when used as directed;

That the *Flushem* when used as directed would be effective in the prevention and treatment of mold poisoning and for the condition known as "Mycosis";

That the *Getsem Poultry Wormer* when used as directed had some specific value in the removal of all species of worms, and more specifically roundworms and pinworms; that it would be effective in the treatment of paralysis; and that it would be effective for better health, growth, and vitality, and for obtaining more eggs from layers.

DISPOSITION: December 5, 1949. Dr. Jespersen's Laboratories, claimant, having withdrawn its claim of ownership and disclaimed any intention of filing an

answer, judgment was entered and the court ordered that the products be destroyed.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3001 TO 3020

PRODUCTS

	N. J. No.		N. J. No.
Air purifiers, Pur-Ar-Lite-----	¹ 3018	Inhalers, eucalyptus compound	
Amberin-----	3015	combination-----	3016
Amphetamine hydrochloride tablets-----	3001	Kimko-----	3011
Arthritis, remedy for-----	3010	Laxative without required warning statements-----	3004
Benadryl capsules-----	3002	Lin-Ox-Ol-----	3013
Cathartein Compound Tablets-----	3005	Lung Remedy, Patrick's-----	² 3007
Colusa Natural Oil Capsules and Colusa Natural Oil-----	3009	Nelson's Hygienic Powder-----	² 3006
D-E Plex Capsules-----	3008	Nue-Ovo-----	3010
D-O-D-----	3012	Patrick's Lung Remedy-----	² 3007
D. R. D. Concentrate-----	3020	Phenobarbital tablets-----	3002
Devices-----	¹ 3016-3019	Poultry Wormer, Getsem-----	3020
Diabetes, remedy for-----	3014	Pur-Ar-Lite Air Purifiers-----	¹ 3018
Eucalyptus compound and inhalers-----	3016	Rheumatism, remedy for-----	3010
Flushem-----	3020	Se-Bex Tablets-----	3008
Fowlton-----	3020	Sulfathiazole lozenges-----	3002
Gall-Klenz-----	3004	Theraplate (device)-----	3019
Geo-Mineral-----	3003	Tox Eliminator devices-----	¹ 3017
Getsem Poultry Wormer-----	3020	Tuberculosis, remedy for-----	² 3007
Hemorrhoids, remedy for-----	3015	Vegex Extract-----	3014
Hygienic Powder, Nelson's-----	² 3006	Veterinary preparations-----	3020
		Vitamin preparations-----	3008
		Worms, remedy for (veterinary preparation)-----	3020

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N. J. No.		N. J. No.
Albright, Glen:		F. A. R. Chemical Co.:	
Tox Eliminator devices-----	¹ 3017	Gall-Klenz-----	3004
Amberin Co.:		Geo-Mineral Co.:	
Amberin-----	3015	Geo-Mineral-----	3003
American Metal Industries:		Great Lakes Pharmacal Corp.:	
Theraplate (device)-----	3019	Nelson's Hygienic Powder-----	3006
Chaffin, Argus:		Hiller, P. M.:	
Benadryl capsules, sulfathiazole lozenges, and phenobarbital tablets-----	3002	Nelson's Hygienic Powder-----	¹ 3006
Circlite Corp.:		Infra-Appliances Corp.:	
Pur-Ar-Lite Air Purifiers-----	¹ 3018	Theraplate (device)-----	3019
Colusa Remedy Co.:		Jespersen's, Dr., Laboratories:	
Colusa Natural Oil Capsules and Colusa Natural Oil-----	3009	Fowlton, D. R. D. Concentrate, Flushem, and Getsem Poultry Wormer-----	3020
		Kimko Co.:	
		Kimko-----	3011

¹ (3017, 3018) Seizure contested. Contains findings of fact and conclusions of law.

² (3006, 3007) Prosecution contested.

	N. J. No.		N. J. No.
Lin-Ox-Ol Sales Corp.:		Vitamin Industries, Inc.:	
Lin-Ox-Ol -----	3013	Se-Bex Tablets, D-E Plex Cap-	
Patrick, Lewis:		sules, and vitamin A cap-	
Patrick's Lung Remedy-----	² 3007	sules-----	3008
Research Laboratories, Inc.:		Vitamin Store:	
Nue-Ovo -----	3010	Se-Bex Tablets, D-E Plex Cap-	
Sandy Sales Co.:		sules, and vitamin A cap-	
eucalyptus compound and in-		sules-----	3008
halers-----	3016	Wear, Cleo:	
Smith, C. Nelson, Co.:		Benadryl capsules, sulfathia-	
D-O-D-----	3012	zole lozenges, and phenobar-	
Standard Chemical Co.:		bital tablets-----	3002
Cathartein Compound Tablets--	3005	West End Drug Store. <i>See</i>	
Stanley Drug Products Co.:		Chaffin, Argus.	
Amberin -----	3015	Wirth, C. R.:	
Tox Eliminator Co., Inc.:		amphetamine hydrochloride	
Tox Eliminator devices-----	¹ 3017	tablets -----	3001
Vegex Co.:		Wirth Drug Store. <i>See</i> Wirth,	
Vegex Extract-----	3014	C. R.	
Vi-Jon Laboratories, Inc.:			
Geo-Mineral -----	3003		

¹ (3017, 3018) Seizure contested. Contains findings of fact and conclusions of law.

² (3006, 3007) Prosecution contested.



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FEDERAL SECURITY AGENCY**FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3021-3040

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., July 6, 1950.

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*For presence of a habit-forming narcotic without warning statement, see No. 3022; omission of, or unsatisfactory, ingredients statements, Nos. 3021, 3022, 3024, 3039; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3021, 3022, 3024, 3039, 3040; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, No. 3021; cosmetics, actionable under the drug provisions of the Act, Nos. 3024, 3034, 3037.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS *

3021. Misbranding of Metro-Vac. U. S. v. Charles A. C. Faiman (Physicians Rx Products), and Dr. F. H. Jordan. Pleas of not guilty. Tried to a jury; verdict of guilty as to defendant Faiman and not guilty as to defendant Jordan. Sentence of two years in prison against defendant Faiman. Judgment affirmed on appeal. (F. D. C. No. 25563. Sample Nos. 22351-K, 27247-K.)

INDICTMENT RETURNED: September 23, 1948, Northern District of Texas, against Charles A. C. Faiman, alias A. C. Faiman, alias C. A. C. Faiman, alias Dr. C. Andrew Faiman, and alias Dr. Charles C. Faiman, trading as Physicians Rx Products, and against Dr. F. H. Jordan, Dallas, Tex.

ALLEGED SHIPMENT: The indictment alleged in count 1 that both defendants, on or about January 24, 1948, willfully and unlawfully caused a quantity of *Metro-Vac* to be introduced and delivered for introduction into interstate commerce at Dallas, Tex., for delivery to Monroe, La. The indictment alleged in count 2 that the defendant Faiman, on or about January 27, 1948, willfully and unlawfully caused a quantity of *Metro-Vac* to be introduced and delivered for introduction into interstate commerce at Dallas, Tex., for delivery to Helena, Ark.

PRODUCT: Analysis showed that the product was a soft potassium soap containing 2.5% of potassium iodide and a crystal violet dye. It was represented to be a uterine evacuant.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the article bore no label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), it bore no label containing an accurate statement of the quantity of the contents; Section 502 (e) (2), it bore no label containing the common or usual name of each active ingredient; Section 502 (f) (1), it bore no labeling containing directions for use; and, Section 502 (f) (2), it bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration or application.

DISPOSITION: On September 30, 1948, the defendants entered pleas of not guilty, and the case immediately proceeded to trial before a jury. On October 1, 1948, the jury returned a verdict of guilty against defendant Faiman and a verdict of not guilty against defendant Jordan, and on the same day the court imposed a sentence of two years in prison against defendant Faiman. An appeal was taken to the U. S. Court of Appeals for the Fifth Circuit on behalf of defendant Faiman, and on March 20, 1950, a decision was handed down by that court, affirming the judgment of the lower court.

3022. Misbranding of Benadryl capsules, Hexital tablets, and Carbrital capsules. U. S. v. Thompson D. Adcock and John G. Malley. Pleas of guilty. Fines of \$125 against defendant Adcock and \$50 against defendant Malley. (F. D. C. No. 26710. Sample Nos. 26183-K, 27029-K, 27031-K, 27041-K, 27044-K, 27315-K, 27532-K.)

INFORMATION FILED: August 19, 1949, Western District of Missouri, against Thompson D. Adcock, a pharmacist for the McGreevy Drug Co. No. 2, a partnership, Springfield, Mo., and against John G. Malley, a partner in the partnership.

*See also No. 3039 (veterinary preparations).

INTERSTATE SHIPMENT: Between the approximate dates of April 18, 1945, and December 11, 1947, from the States of Michigan and New Jersey into the State of Missouri.

LABEL, WHEN SHIPPED: "Kapseals Benadryl Hydrochloride [or "Kapseals Carbrital"] * * * Caution—To be dispensed only by or on the prescription of a physician" and "Hexital Caution—To be used only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about April 20, July 8 and 10, August 9 and 13, and September 20 and 23, 1948, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused a number of capsules and tablets of the drugs to be removed from the bottles in which they had been shipped and to be repacked and sold to various persons without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded. The repackaged drugs were labeled in part "Benadryl Capsules 50 MG," "Hexital," and "Carbrital Capsules."

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the labels of the repackaged drugs bore no statement of the quantity of the contents; and, Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use.

Further misbranding, Section 502 (e) (2), the labels of the repackaged *Hexital tablets* and the repackaged *Carbrital capsules* failed to bear the common or usual name of each active ingredient of the drugs, namely, phenobarbital and Hexestrol, in the *Hexital tablets*, and pentobarbital sodium and carbromal, in the *Carbrital capsules*.

Further misbranding, Section 502 (d), the repackaged *Hexital tablets* and *Carbrital capsules* were drugs for use by man and contained chemical derivatives of barbituric acid, which derivatives had been, by the Administrator of the Federal Security Agency, after investigation, found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: November 18, 1949. Pleas of guilty having been entered, the court imposed a fine of \$25 on each of 5 counts against defendant Adcock, covering the sales personally made by him, and a fine of \$25 on each of 2 counts against defendant Malley, relating to the sales which he had made personally.

3023. Misbranding of Elodex. U. S. v. 3 Cases * * *. (F. D. C. No. 28039. Sample No. 48536-K.)

LABEL FILED: On or about October 17, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about September 30, 1949, from New York, N. Y.

PRODUCT: 3 cases, each containing 28 10-ounce packages, of *Elodex* at Vine-land, N. J., in possession of the Neptune Health Products.

This product was represented by Rudy Holmberg, proprietor of the Neptune Health Products, during lectures delivered by him at the Trenton State Fair, Trenton, N. J., on September 30, 1949, to be effective in helping relieve the user of rheumatism and in preventing colds, rheumatism, lumbago, arthritis, and neuritis, for which no adequate directions for use appear in its labeling.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 18, 1949. Default decree of condemnation and destruction.

3024. Misbranding of miscellaneous salvaged drugs. U. S. v. 25 Crates, etc. (F. D. C. No. 27154. Sample No. 62100-K.)

LIBEL FILED: April 21, 1949, District of Massachusetts.

ALLEGED SHIPMENT: On or about April 17, 1948, by the Underwriter Salvage Co. of New York, from Providence, R. I.

PRODUCT: 25 crates and 36 cartons of miscellaneous salvaged drugs at West Lynn, Mass. A portion of the material had been fire-damaged. Some bottles and jars were unlabeled; in some bottles a number of tablets had partially disintegrated; and in some bottles a number of tablets had fused and adhered to the bottoms of the bottles.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the labels of the articles failed to bear accurate statements of the quantity of the contents; Section 502 (e) (2), the articles were fabricated from two or more ingredients, and their labels failed to bear the common or usual names of the active ingredients; and, Section 502 (f) (2), the labeling of the articles failed to bear adequate warnings against use in those pathological conditions and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration and application.

The libel alleged also that certain products included in the shipment were misbranded under the provisions of the law applicable to foods and cosmetics, as reported in notices of judgment on foods, No. 15648, and in notices of judgment on cosmetics. (The notice of judgment on cosmetics will be issued at a later date.)

DISPOSITION: May 26, 1949. The Triangle Sales Corp., Lynn, Mass., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond, to be brought into compliance with the law, under the supervision of the Federal Security Agency. The unfit portion of the products was segregated and destroyed.

3025. Misbranding of Spectro-Chrome devices. U. S. v. 1 Device * * * (and 29 other seizure actions). (F. D. C. Nos. 25039, 25040, 25059 to 25070, incl., 25118 to 25120, incl., 25125, 25126, 25128, 25129, 25131 to 25135, incl., 25208, 25220, 25252, 25273. Sample Nos. 14001-K to 14018-K, incl., 14478-K to 14484-K, incl., 15549-K, 18249-K, 18253-K, 24624-K, 37078-K.)

LIBELS FILED: Between July 14, 1948, and February 15, 1949, Eastern and Western Districts of Wisconsin, Eastern District of Washington, Eastern District of Michigan, and Northern District of Ohio.

ALLEGED SHIPMENT: Between the approximate dates of December 19, 1947, and March 8, 1948, by Dinshah P. Ghadiali and the Dinshah Spectro-Chrome Institute, from Malaga, N. J.

PRODUCT: 30 *Spectro-Chrome* devices at Colfax, El Dorado, Milwaukee, Fond du Lac, and Newton, Wis.; Detroit, Flat Rock, Hamtramck, Wyandotte, Dearborn, Lenox, and Royal Oak, Mich.; Liberty, Wash.; and Cleveland and Euclid, Ohio.

Examination showed that the device consisted essentially of a cabinet equipped with a 1,000-watt floodlight bulb, an electric fan, a container for water for cooling purposes, two glass condenser lenses for concentrating the light, and a number of glass slides of different colors.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the device failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: Between the dates of October 26, 1948, and December 27, 1949. The following-named individuals in possession of the devices refused to surrender them when the marshal first attempted to make seizure: Walter Chandler, Mrs. Blanch C. Leighton, Mrs. Kate Kirsammer, William Cunningham, Joseph Lipinski, John A. McDougall, John B. Cunningham, Fred Petsch, and Stella Hitkowski, all of Detroit, Mich.; Mrs. Anna Cabaj, Hamtramck, Mich.; Mrs. Victoria Dabrowa, Wyandotte, Mich.; Dorothy Westphol, Dearborn, Mich.; and Joseph A. Lull, Milwaukee, Wis. However, the Government instituted proceedings in the appropriate courts, which resulted in the issuance by the courts of orders to each of the individuals, upon the receipt of which the 13 devices involved were surrendered. Counsel representing several of the above-named individuals, and also another consignee of Detroit, Mich., intervened, whereupon on motion of the Government's attorneys, orders were entered directing the individuals to post security for costs. The orders provided that failure to post such security would effect a default, entitling the Government to judgment. Since no answers were filed and no security for costs was posted, defaults were duly noted.

No claimant appeared for the devices involved in the remaining actions, with the exception that Jack Kirsch, Liberty, Wash., appeared as the claimant for the device seized at that point. Mr. Kirsch filed an answer denying the misbranding of the device, but subsequently admitted the allegations of the libel and consented to the entry of a decree.

Decrees of condemnation were entered in all cases, and the courts ordered that the devices be destroyed, with the exception of four that were ordered delivered to the Food and Drug Administration.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3026. Adulteration of dextro-amphetamine hydrochloride tablets. U. S. v. 52,000 Tablets * * *. (F. D. C. No. 28751. Sample No. 47649-K.)

LABEL FILED: March 9, 1950, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about August 29, 1949, by Hance Bros. & White Co., from Philadelphia, Pa.

PRODUCT: 52,000 *dextro-amphetamine hydrochloride tablets* at Norfolk, Va.

LABEL, IN PART: (Drum) "C. T. 'Pale Yellow' Each containing: d-Amphetamine HCl. 5 Mg."; (portion repackaged into bottles) "Dexo-Tabs Each Tablet Contains Dextro-Amphetamine Hydrochloride 5 Mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, d-amphetamine hydrochloride 5 mg. (Examination disclosed that the tablets contained not more than 4.15 milligrams of dextro-amphetamine hydrochloride.)

DISPOSITION: March 30, 1950. Default decree of condemnation and destruction.

3027. Adulteration of peppermint leaves, powdered capsicum, and Hungarian chamomile. U. S. v. 1 Bag, etc. (F. D. C. No. 28048. Sample Nos. 11777-K, 11779-K, 11780-K.)

LIBEL FILED: October 18, 1949, District of Connecticut.

ALLEGED SHIPMENT: On or about August 24 and 29 and September 8, 1949, from New York, N. Y.

PRODUCT: 1 bag containing 31 pounds of *peppermint leaves*, 1 drum containing 25 pounds of *powdered capsicum*, and 66 pounds in bulk and 136 cases, each case containing 720 1-ounce packages, of *Hungarian chamomile*, at Fairfield, Conn.

NATURE OF CHARGE: Adulteration, Section 501 (b), the products purported to be and were represented as drugs the names of which are recognized in official compendiums, and their purity and quality fell below the official standards since they contained insects, insect fragments, and rodent hairs. The standards provide that vegetable drugs are to be as free as practicable from molds, insects, and other animal contamination, and animal excreta. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: January 11, 1950. Default decree of condemnation and destruction.

3028. Adulteration of oil of theobroma. U. S. v. 694 Bottles * * *. (F. D. C. No. 28460. Sample No. 11702-K.)

LIBEL FILED: December 8, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about February 8, 1949, by the Royal Sundries Corp., from New Brunswick, N. J.

PRODUCT: 694 2-ounce bottles of *oil of theobroma* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "theobroma oil," a drug the name of which is recognized in the United States Pharmacopoeia, and its quality and purity fell below the official standard since it had a rancid, acrid odor and a rancid taste. The standard provides that *theobroma oil* has a faint, agreeable odor and a bland taste.

DISPOSITION: January 25, 1950. Default decree of condemnation and destruction.

3029. Adulteration and misbranding of prophylactics. U. S. v. 252 Gross * * *. (F. D. C. No. 28466. Sample Nos. 56599-K, 56600-K.)

LIBEL FILED: December 5, 1949, Eastern District of New York.

ALLEGED SHIPMENT: On or about October 31, 1949, by Central Sundries, Inc., from East Newark, N. J.

PRODUCT: 252 gross of *prophylactics* at Brooklyn, N. Y. Examination of samples showed that 2.4 percent were defective in that they contained holes.

LABEL, IN PART: (Package) "Package of Two Royal Knight Prophylactics."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label designation "Prophylactics" was false and misleading as applied to an article containing holes.

DISPOSITION: January 27, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3030. Misbranding of Atomic Botanical Laxative Compound. U. S. v. 117 Bottles, etc. (F. D. C. No. 28475. Sample No. 53797-K.)

LIBEL FILED: December 12, 1949, Northern District of Alabama.

ALLEGED SHIPMENT: The drug was shipped on or about September 26, 1949, by the General Products Laboratories, from Columbus, Ohio, and a number of booklets were shipped on or about September 27, 1949, by Atomic Distributors, Inc., from Miami, Fla.

PRODUCT: 117 16-ounce bottles of *Atomic Botanical Laxative Compound* at Birmingham, Ala., together with a number of booklets entitled "This Free Booklet Contains Important News." Analysis showed that the product consisted essentially of extracts of plant drugs, including laxative plant drugs.

LABEL, IN PART: "Atomic Botanical Laxative Compound Internal Medicine
* * * Atomic Distributors, Inc. Columbus, Ohio."

NATURE OF CHARGE: Misbranding, Section 502 (a), the word "Atomic" appearing on the label of the article and certain statements in the booklet were false and misleading. The word and the statements represented and suggested that the article possessed atomic energy, and that a laxative would be effective in promoting health and relieving coated tongue, bad breath, loss of appetite and energy, sleeplessness, nervousness, headaches, sallow complexion, pimples, blackheads, indigestion, and many other such serious conditions. The article did not possess atomic energy, and a laxative is not effective in promoting health and relieving the diseases and conditions stated.

DISPOSITION: January 13, 1950. Default decree of condemnation and destruction.

3031. Misbranding of Harmon's Compound. U. S. v. 131 Bottles * * *. (F. D. C. No. 27271. Sample No. 1440-K.)

LIBEL FILED: May 26, 1949, Middle District of North Carolina; libel amended on or about October 21, 1949.

ALLEGED SHIPMENT: On or about April 6, 1949, from Cincinnati, Ohio.

PRODUCT: 131 12-ounce bottles of *Harmon's Compound* at Winston-Salem, N. C., in possession of the Standard Sales Co., together with a number of circulars entitled "Here It Is—Harmon's Compound," which were printed locally for the dealer and displayed on the sales counter near the product.

Analysis showed that the product consisted essentially of epsom salt, sodium phosphate, and water, with small proportions of iron salts and flavoring materials.

*See also No. 3029.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying circulars were false and misleading since the article was not effective in the treatment of the conditions stated and implied. The statements represented and suggested that the article would be efficacious for the relief of indigestion and gas; that it would be efficacious in the cure, mitigation, treatment, and prevention of sour stomach, heartburn, belching, and bloating, nervous, dizzy spells, headaches, eyestrain, rheumatism, arthritis, neuritis, pimples, boils, rashes, skin eruptions, nervousness, sleeplessness, high blood pressure, anemia, catarrh, sinus trouble, distress after eating, acid stomach, liver, kidneys, and bladder, and intestinal disorders, colds, rheumatic muscular aches and pains in the feet, legs, hips, arms, and shoulders; that the article would raise total vitality, boost muscle power, restore manly vigor, and bring back that glad to be alive feeling; and that it was a youth restorer. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 15, 1949. The Standard Sales Co., claimant, having filed an answer denying the allegations of the libel, but subsequently having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

3032. Misbranding of Elemin Tablets. U. S. v. 71 Bottles, etc. (F. D. C. No. 27997. Sample No. 60443-K.)

LIBEL FILED: September 23, 1949, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about August 15, 1949, by G & J Distributors, from Berkeley, Calif.

PRODUCT: 71 700-tablet bottles and 67 240-tablet bottles of *Elemin Tablets* at Milwaukee, Wis., in possession of SMS Distributors, together with a number of copies of a booklet entitled "Facts You Should Know About Elemin." The booklets were printed in Milwaukee by copying the text of printed matter sent to SMS Distributors by G & J Distributors.

LABEL, IN PART: (Bottle) "Elemin As a Source of the Minerals Iron and Iodine Contains: Iodine and Iron as naturally present in dehydrated kelp, iron gluconate and a Sedimentary Mineral Deposit."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the booklets were false and misleading since the article was not effective for the purposes stated and implied. The statements represented and suggested that the article was effective to prevent and correct pyorrhea, gingivitis, poor teeth, tooth decay, arthritis, hemorrhoids, chronic bronchitis, acne vulgaris, pimples, epilepsy, constipation, asthma, hay fever, eczema, nervousness, run-down condition, insomnia, anemia, rheumatic fever, diabetes, poor circulation, high and low blood pressure, undulant fever, indigestion, old-age deposits, poor resistance, mental fatigue, liver disorders, hyperacidity, glandular troubles, poor eyesight, baldness, gray hair, skin disorders, sterility, lameness, stomach ulcers, bone deformities, rickets, tuberculosis, chronic gastritis, indigestion, heart disease, neuritis, and lumbago. The article was misbranded when introduced into, while in, and while held for sale after shipment in interstate commerce.

DISPOSITION: November 4, 1949. A default decree was entered, providing for condemnation of the product and its disposition in accordance with the further order of the court. On November 18, 1949, the product was destroyed by the marshal.

3033. Misbranding of Vita Orange. U. S. v. 21 Cases * * * (and 1 other seizure action). (F. D. C. Nos. 28288, 28321. Sample Nos. 63019-K, 63033-K.)

LIBELS FILED: November 14 and 25, 1949, District of Maine.

ALLEGED SHIPMENT: On or about October 7 and November 4, 1949, by the California Fruit Juice Co., from Waltham, Mass.

PRODUCT: 85 cases, each containing 6 ½-gallon jugs, of *Vita Orange* at Wells and Waterville, Maine. Examination showed that the product was a mixture of orange juice, orange oil, water, acid, sugar, and artificial color.

LABEL, IN PART: (Jug) "Vita Orange with Vitamins added."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name "Vita Orange" on the bottle label and certain statements in an accompanying circular entitled "The Good Morning to Health" were false and misleading. The name and the statements represented and suggested that the article was nutritionally better than orange juice; that it was a better source of vitamins than orange juice; that it would be effective to promote health, healthy bones, teeth, and gums; and that it would be effective in the treatment of colds and in the prevention of infections. The article was not nutritionally better than orange juice; it was not a better source of vitamins than orange juice; and it would not be effective for the purposes represented.

The article was alleged also to be adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 30, 1950. Default decrees of condemnation and destruction.

3034. Misbranding of estrogenic hormone creams. U. S. v. 94 Jars, etc. (F. D. C. No. 27873. Sample No. 57635-K.)

LIBEL FILED: September 21, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about June 15, 18, and 29, and July 20, 1949, by the Up-To-Date Cosmetic Co., from New York, N. Y.

PRODUCT: 94 3-ounce jars and 30 1-ounce jars of *Estron-Hormone Cream*, 30 1-ounce jars of *Estro Turtle Hormone Cream*, and 81 1-ounce jars of *Estrogenic Hormone Cream* at Newark, N. J., together with a number of circulars entitled "Help Nature As The Years Pass By!" and a number of placards entitled "Estro-Turtle Cream."

LABEL, IN PART: "Estron-Hormone Cream with Petrolatum, Lanolin Mexican Turtle Oil * * * contains 7,500 units of natural estrogenic hormones per ounce, with 85% estrone," "Estro Turtle Hormone Cream with Lanolin * * * contains 7,500 int. units of natural estrogenic hormones," and "Estrogenic Hormone Cream Cont. 7,500 IU nat. estrogenic hormones per oz. (85% estrone)."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the articles were false and misleading since the articles were not effective in the conditions or for the purposes stated and implied: (Estron-Hormone Cream) "To help freshen the appearance of faded and aged skin" and "These ingredients contain the glandular oils, present in young skins, which day by day diminish after 30 years of age. It helps to erase throat lines, neck lines and eye lines—and helps stimulate undernourished

skin and flabbiness on the face, neck or any part of the body," (Estro Turtle Hormone Cream) "1) It helps to remove eye lines age-lines. 2) It helps to firm up sagging muscles, double chin and crepey throats. 3) It helps to stimulate undernourished skin and brings back fresh and youthful glow to faded face and neck-skin," and (Estrogenic hormone cream) "helps to erase eye lines, large pores and skin impurities. Helps to stimulate undernourished skin and brings back freshness to faded face and neck."

DISPOSITION: November 17, 1949. Default decree of condemnation. The court ordered that a portion of the products be delivered to the Food and Drug Administration and that the remainder be destroyed.

3035. Misbranding of St. Johns 4 Way Hair Grower and Scalp Treatment. U. S. v. 12 Bottles, etc. (F. D. C. 27217. Sample No. 47706-K.)

LIBEL FILED: May 16, 1949, Southern District of West Virginia.

ALLEGED SHIPMENT: The product and a number of leaflets and display cards were shipped on or about March 12 and April 1 and 5, 1949, by the St. Johnsbury Products Co., from Los Angeles, Calif., and a number of other leaflets were shipped by the Dispatch Printing Co., from Los Angeles, Calif., on or about March 30, 1949.

PRODUCT: 12 8-ounce bottles of *St. Johns 4 Way Hair Grower and Scalp Treatment* at Charleston, W. Va., together with a number of leaflets entitled "Announcing The Discovery of St. Johns 4 Way Hair Grower and Scalp Treatment" and "Jack Chefe" and a number of display cards entitled "A New Discovery."

LABEL, IN PART: "St. Johns 4 Way Hair Grower and Scalp Treatment * * *
Ingredients: Prepared with Complex Glucosides, Sodium Bicarbonate, Sodium Sulfate, Sodium Chloride, and Ferric Chloride."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in the leaflets and on the display cards were false and misleading since they represented and suggested that the article was effective in growing hair on bald heads, stopping the loss of hair, and curing dandruff and scalp itch, whereas the article was not effective for such purposes.

DISPOSITION: December 19, 1949. The St. Johnsbury Products Co., claimant, having filed an answer and the answer subsequently having been withdrawn, judgment of condemnation was entered and the court ordered that the product be destroyed.

3036. Misbranding of Jessamine's Electro-Way (device). U. S. v. 1 Device * * *. (F. D. C. No. 28303. Sample No. 55296-K.)

LIBEL FILED: On or about December 1, 1949, Western District of Missouri.

ALLEGED SHIPMENT: On or about September 12, 1949, by Jessamine's, from Oakland, Calif.

PRODUCT: 1 *Jessamine's Electro-Way* device at Kansas City, Mo. This device consisted of a transformer to reduce the voltage of the ordinary house current and pads by means of which the low voltage current could be applied to any desired part of the body.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying labeling of the device, namely, in an undated letter mailed September 5, 1949, in letters dated September 20, 1949, and September 29, 1949,

and in 3 pamphlets entitled "Reducing Made Easy," were false and misleading. The statements represented and suggested that the device was effective in bringing about a reduction in weight, development of the breast, removal of wrinkles, correction of sagging muscles, skin stimulation, muscle toning, muscle exercising, and promoting the growth of hair; that it would be effective in the relief of nerve and muscle tension, arthritis, varicose veins, high blood pressure, hypertension, paralysis, constipation, migraine, psoriasis, and headache; that it would be effective to restore hearing, prevent blindness, induce pregnancy, and promote circulation of good blood; and that it would be effective to treat muscle injuries, menstrual cramps, aches and pains, sinus, shingles, and cramps. The device was not effective for such purposes.

DISPOSITION: January 20, 1950. Default decree of condemnation. The court ordered that the device and the accompanying labeling be delivered to the Food and Drug Administration.

3037. Misbranding of *Massage-O-Mat* (device). U. S. v. 1 Device * * *.
(F. D. C. No. 25805. Sample No. 9109-K.)

LABEL FILED. October 6, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about July 20, 1948, by the *Massage-O-Mat* Corp., from New York, N. Y.

PRODUCT: 1 device known as *Massage-O-Mat* at Asbury Park, N. J., together with a number of circulars entitled "A New Beauty and Health Service For You."

This device was an electrically operated mechanical massager. The top, on which the user reclined, was made of some flexible material. Underneath were 270 rubber rollers. The back and forth motion of these rollers pressing against the body through the top covering, rolled and kneaded the body of the user.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the circular were false and misleading since the statements represented and suggested that the device was effective in the treatment of the conditions stated and implied, whereas it was not effective for such conditions: "Health Service * * * to help you to * * * radiant health! * * * a real 'toning' treatment * * * work of stimulating circulation, toning muscles and nerves, relieving tension, and reducing whichever parts of your body you wish. * * * It relieves * * * cramp, and helps you to strong, healthy feet. * * * Massage as the ideal way to reduce * * * take an all-over reducing treatment; or, if you wish you can concentrate on particular parts of the body; or you can do both in one session! * * * will stimulate your general circulation and start the 'toning' process. To Reduce Your Hips * * * To Reduce Your Thighs * * * To Reduce Your Abdomen * * * rollers will do their work of toning and firming the superfluous flesh * * * stimulating circulation, relaxing tight, cramped muscles, easing fatigue and pain * * * the *Massage-O-Mat* to solve your individual figure problems * * * eases tension and fatigue, induces real relaxation, and helps keep you fit * * * the healthful, normal way! Also, the rolling action of the *Massage-O-Mat* duplicates the natural action of the intestines and helps keep you 'regular' * * * use the *Massage-O-Mat* whenever you feel depressed * * * It will help you to health, vitality."

DISPOSITION: January 16, 1950. The *Massage-O-Mat* Corp., claimant, having filed an answer denying that the device was misbranded and subsequently

having withdrawn its answer, judgment of condemnation was entered and the court ordered that the device be destroyed.

3038. Misbranding of parts and accessories for a device called "Farador." U. S. v. 190 Treating Plates, etc. (F. D. C. No. 28007. Sample No. 52434-K.)

LIBEL FILED: October 7, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: A number of parts and accessories, together with a number of circulars, were shipped on or about July 2 and 30, 1949, by Mrs. Florence M. Higley, from Buffalo, N. Y. Additional accessories were shipped on or about June 28, 1949, by E. W. Schlenker, from Buffalo, N. Y., and 26 brass cylinders were shipped on or about August 23, 1949, by the Curtis Screw Co., from Buffalo, N. Y.

PRODUCT: Various parts and accessories for use in assembling "Farador," a device, located at Englewood, Ohio. When the device was assembled, it consisted of a brass cylinder with two wires affixed to one end and various accessories which were to be attached to the free ends of the wires and applied to parts of the body. The device was therapeutically inert. The following items were covered by the libel: 190 treating plates, 55 local plates, 33 foot plates, 10 eye treating plates, 33 end connectors, 6 rectal dilators (large), 91 special urethral applicators, 3 sets ear attachments, 7 eye attachments, 8 rectal dilators (small), 4 female sounds, 1 tooth and mouth plate, 6 spinal plates, 6 partly finished rectal dilators, 9 partly finished mouth plates, 20 sets of Farador ends, 54 Farador sealing rings, 78 lead rings, 32 cork fillers, and 26 brass cylinders.

The circulars accompanying the accessories were entitled "Harnessing Nature," "Guards the Health of the Home," "We Submit Proofs" (white), "We Submit Proofs" (yellow), "Farador Direction Book," "Directions for Using the Farador Mouth Plate" [or "Optical Device," "Spinal Plate," "Dilation Treatment," "Urethral Sound," "Nasal Attachment," "Foot Plate," "Local Plate," or "Back Plate"].

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the accompanying circulars were false and misleading. The statements represented and suggested that the device was adequate and effective for the prevention, treatment, and cure of most of the diseases of the human body, including, but not limited to, appendicitis, blood poison, tuberculosis, syphilis, spinal meningitis, apoplexy, convulsions, sexual debility, epilepsy, gonorrhea, infantile paralysis, malaria, paralysis, and heart disease. The device was not adequate or effective for the prevention, treatment, or cure of the diseases, conditions, and symptoms stated and implied.

DISPOSITION: December 23, 1949. Default decree of condemnation. The court ordered that a number of the accessories and circulars be turned over to the Food and Drug Administration and that the remainder of the accessories and circulars be destroyed.

DRUGS FOR VETERINARY USE

3039. Misbranding of Life Guard Medicated Liquid for Poultry, Life Guard Remrow Water Wormer, Life Guard Medicated Liquid for Hogs, and Life Guard Expeller. U. S. v. Liberty Oil Co. Plea of guilty. Fine of \$175 and costs. (F. D. C. No. 28099. Sample No. 24653-K, 25851-K, 45548-K, 45556-K.)

INFORMATION FILED: January 13, 1950, Southern District of Iowa, against the Liberty Oil Co., a corporation, Des Moines, Iowa.

ALLEGED SHIPMENT: On or about September 24, 1948, and February 2, March 1, and May 3, 1949, from the State of Iowa into the State of Minnesota.

PRODUCT: Analysis disclosed that the *Life Guard Medicated Liquid for Poultry* consisted of a purple-colored aqueous liquid containing essentially salts of potassium, sodium, and aluminum in the form of permanganate, chloride, sulfate, and chlorate; that the *Life Guard Remrow Water Wormer* consisted of an aqueous mixture having considerable sediment and containing essentially 12.8 grams per 100 cc. phenothiazine, together with salts of iron, sodium, calcium, and manganese in the form of chloride, sulfate, carbonate, phosphate, and anise; that the *Life Guard Medicated Liquid for Hogs* consisted of a dark green aqueous liquid with a small amount of brown sediment and containing essentially salts of copper, sodium, manganese, potassium, and aluminum in the form of sulfate, carbonate, and anise; and that the *Life Guard Expeller* consisted of an oil composed essentially of castor oil, 3½ percent oil of chenopodium, and 5.68 grams per 100 cc. of chloroform.

LABEL, IN PART: "Life Guard Brand Medicated Liquid for Poultry [or "Remrow Water Wormer," "Medicated Liquid for Hogs," or "Expeller"]."

NATURE OF CHARGE: *Life Guard Medicated Liquid for Poultry.* Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented that the article would be efficacious in the treatment and prevention of coccidiosis in poultry, whereas it would not be efficacious for such purposes; and, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient.

Life Guard Remrow Water Wormer. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article would be effective in the removal of all species of worms from hogs, sheep, horses, poultry, and pet stock, whereas it would not be effective for such purpose; and the statement on the label of the active ingredients of the article, namely, "Active Ingredients Phenothiazine, Ferrous Sulphate, Sodium Carbonate, Calcium Hydroxide, Magnesium Sulphate, Potassium Permanganate, Manganese Chloride, Potassium Phosphate," was false and misleading since the article contained only one active ingredient, phenothiazine. Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health since the article contained phenothiazine, and its labeling failed to warn that occasional individual sensitiveness of animals to phenothiazine has been reported, and that sick, feverish, or physically weak animals, especially horses, should not be treated with a product containing phenothiazine, except upon the advice of a veterinarian.

Life Guard Medicated Liquid for Hogs. Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article when used as directed would have significant medicinal value for hogs, whereas the article when used as directed would have no significant medicinal value for hogs.

Life Guard Expeller. Misbranding, Section 502 (b) (2), the label of the article bore no statement of the quantity of the contents; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed

to bear the common or usual name of each active ingredient, including the name and quantity or proportion of chloroform contained in the article, since the label bore no statement of the ingredients contained in the article; and, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health since the article contained oil of chenopodium, and its labeling failed to warn that a product containing oil of chenopodium should not be administered to sick, feverish, physically weak, or undernourished animals, except upon the advice of a veterinarian.

DISPOSITION: January 24, 1950. A plea of guilty having been entered, the court imposed a fine of \$175 and costs.

3040. Misbranding of Poultry Compound, Master-Mix Mineral Feed for Cattle, Dry Insecticide Dip, National Mange Oil, National Compound for Hogs, National Compound for Sheep, National Mineralized Yeast Feeds, and Guai-Calyptol. U. S. v. 1 Carton, etc. (F. D. C. No. 27272. Sample Nos. 44583-K to 44587-K, incl., 44589-K to 44591-K, incl.)

LABEL FILED: June 3, 1949, District of Minnesota.

ALLEGED SHIPMENT: On or about October 1948, and January 15, February 1, March 11 and 15, and April 21, 1949, by the National Compound Co., from Sioux Falls, S. Dak.

PRODUCT: 1 7-pound carton of *Poultry Compound*, 2 100-pound bags of *Master-Mix Mineral Feed for Cattle*, 2 6-pound cartons and 5 15-pound cartons of *Dry Insecticide Dip*, 19 50-pound sacks of *National Compound for Hogs*, 1 50-pound sack of *National Compound for Sheep*, 7 50-pound sacks of *National Mineralized Yeast Feeds*, 4 5-gallon cans of *National Mange Oil*, and 7 16-ounce bottles of *Guai-Calyptol* at Ellsworth, Minn., together with a number of circulars entitled "Hog Feeding Suggestions," "Don't Waste the Hogs," "National Yeast Feeds," and "Master Mix Mineral for Better Cattle Feeding."

LABEL, IN PART: "Poultry Compound Including Kamala * * * Foenu-greek, Quassia, Bicarbonate of Soda, Tobacco—containing Nicotine-Sulphate, Kamala, Two per cent Areca Nuts, Oil of Wormseed, Sodium Sulphate, Iron Sulphate, Sulphur, Charcoal and Iron Oxide," "Master Mix Mineral Feed for Cattle * * * Bicarbonate of Soda, Sulphate of Soda, Sodium Chloride, Sulphur, Charcoal, Rock Phosphate, Ground Limestone (98% Carbonate of Calcium), Oil Cake—Linseed or Soybean Meal, Steamed Bone Meal, Quassia, Anise, Iodine," "Dry Insecticide Dip * * * Active Ingredients Napthalene -- about 30% Sodium Fluoride -- 1% Sulphur -- 30% Inert Ingredients -- 39%," "National Compound for Hogs * * * Areca Nuts 2%, Quassia Chips, Oil of Chenopodium—or Wormseed, Foenu-greek, Anise—or its Extracted Oil, Copper Sulphate .5%, Charcoal, Linseed Oil Cake Meal—used as a mixing vehicle, 8%, Flour of Sulphur, Bicarbonate of Soda, Sulphate of Sodium, Sugar, Sulphate of Iron," "National Compound for Sheep * * * Areca Nuts, 2%, Quassia, Oil of Wormseed, Oil of Anise, Oxide of Iron, Charcoal, Sulphur, Bicarbonate of Soda, Sodium Chloride, Kamala, Tobacco, Foenu-greek, Glauber Salt, Sulphate of Iron," "Mineralized Yeast Feeds * * * Iodized Limestone (98% Calcium Carbonate), Licorice, Rock Phosphate with Colloidal Clay, Wheat Middlings, Alfalfa Meal, Soybean Oil Meal, Bicarbonate of Soda, Sodium Chloride—salt—, Charcoal, Bone Meal, Yeast, Glauber Salt," "National Mange Oil * * * Paraffin Oil 96%, Pine Oil 2%, Cresylic Acid

2%," and "Guai-Calyptol * * * Cresyllic Acid 4½%, Guaiacol, Eucalyptol, Pine Oil, Camphor, and Eugenol, with a Saponified Inert Base."

NATURE OF CHARGE: Misbranding. Section 502 (a), certain statements on the labels of the articles and in the accompanying circulars were false and misleading. These statements represented and suggested:

That the *Poultry Compound* would be efficacious in the removal of worms from all kinds of poultry, and that it would be efficacious as an aid to greater egg production and as a tonic and regulator;

That the *Master-Mix Mineral Feed for Cattle* would be efficacious in the cure, mitigation, treatment, and prevention of lump jaw, broken bones, bad teeth, wobbling gaits in younger cattle, and trouble connected with the assimilating system; that it would be efficacious for better health, faster growth, and better digestive action; that it would be efficacious in curbing contagious abortion; that it would keep the stomach clean and sweet, prevent constipation, eliminate occasional bad feed disturbances, and keep the internal organs in a healthier condition; that it was a blood purifier; and that it consisted of minerals;

That the *Dry Insecticide Dip* was effective as a general disinfectant for use about the house, barn, and hen house, and that it was efficacious in the treatment of "flu" in hogs;

That the *National Compound for Hogs* would increase the appetite, aid digestion, expel worms, increase assimilation, regulate the bowels, promote thrift, aid vigor, and aid in preventing diseases; that it was efficacious as a tonic, stimulator, and general conditioner; that it would be efficacious to insure a free and regular bowel action; that it would be efficacious in the treatment of scours in young pigs; that it would be efficacious to prevent white scours and to keep the brood sow in nice shape during the pigging season; that it would be efficacious in the prevention of necro; that use of the article would enable the hog to fatten in a month's less time and make a saving of one-fifth in his feed; and that the article would keep the pig in the pink of condition from suckling time to selling;

That the *National Compound for Sheep* would be effective in stimulating the appetite, eliminating gases, speeding digestion, adding to thrift and vigor, and expelling worms, and that it would be effective as a tonic and as a conditioner of sheep;

That the *National Mineralized Yeast Feeds* would make healthier hogs with bigger appetites; that it would promote vigor and tone and aid digestion and assimilation; that it would assist the stomach and other internal organs in the assimilation of the pork making elements in the usual farm feeds; that it would clear out practically all bowel troubles; that it would increase egg production and make healthier baby chicks; and that it would be efficacious in the treatment of bowel troubles in young chicks and in mature hens;

That the *National Mange Oil* would be efficacious in the treatment and prevention of mange on hogs, horses, and cattle; that it was a sure cure for lice and mites on hogs, chickens, cattle, horses, dogs, and other domestic animals; that it would kill fleas, ticks, and bugs, and destroy and prevent the hatching of their eggs; that it would be efficacious in the treatment and prevention of coughs in hogs; and that it would be efficacious as an antiseptic dressing for cuts, wounds, and sores of farm animals, and as a preparation possessing great healing power for all infections of the skin;

That the *Guai-Calyptol* would be efficacious in the treatment of flu and colds in poultry and livestock.

The statements referred to above were false and misleading since the articles would not be effective for the purposes represented, and the *Master-Mix Mineral Feed for Cattle* contained nonmineral ingredients, namely, charcoal, oil cake, quassia, and anise.

Further misbranding, Section 502 (b) (2), the *Poultry Compound* and the *National Mange Oil* bore no declarations on their labels of the quantity of the contents.

The *National Mange Oil* and the *Guai-Calypsol* were misbranded while held for sale after shipment in interstate commerce. (The products were relabeled by the dealer with labels mailed to him by the shipper.) The other articles were misbranded when introduced into, and while in, interstate commerce.

DISPOSITION: October 5, 1949. Default decree of destruction.

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SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

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¹ (3021) Prosecution contested.

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parts and accessories for Fara-dor device-----	3038	Standard Sales Co.:	
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¹ (3021) Prosecution contested.

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4 miles	40	20
5 miles	50	25
6 miles	60	30
7 miles	70	35
8 miles	80	40
9 miles	90	45
10 miles	100	50

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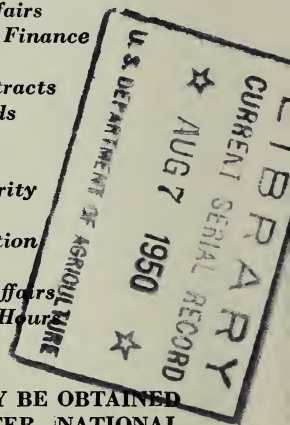
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FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3041-3060

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., August 3, 1950.

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*For presence of a habit-forming narcotic without warning statement, see Nos. 3042, 3043; omission of, or unsatisfactory, ingredients statements, Nos. 3041-3043; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3041-3044; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3041-3043.

**DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE
DIRECTIONS OR WARNING STATEMENTS**

3041. Misbranding of Dexedrine Sulfate Tablets and Benzedrine Sulfate Tablets. U. S. v. Armand G. Crawford (Crawford Pharmacies), Carl Hendricks, and Garland A. Butt. Pleas of nolo contendere. Defendants placed on probation for 1 year. (F. D. C. No. 26734. Sample Nos. 45561-K, 45562-K, 46183-K, 46187-K, 46233-K, 46234-K.)

INFORMATION FILED: September 26, 1949, Western District of Arkansas, against Armand G. Crawford, trading as Crawford Pharmacies, and Carl Hendricks and Garland A. Butt, pharmacists.

INTERSTATE SHIPMENT: Prior to the date of the sales of the *Dexedrine Sulfate Tablets* and the *Benzedrine Sulfate Tablets* by the defendant as hereinafter described, the tablets were shipped in interstate commerce from the State of Pennsylvania into the State of Arkansas.

LABEL, WHEN SHIPPED: (On number of bottles) "Dexedrine Sulfate Tablets * * * Caution: To be dispensed only by or on the prescription of a physician" or "Benzedrine Sulfate Tablets * * * Caution: To be dispensed only by or on the prescription of a physician."

ALLEGED VIOLATION: On or about December 30, 1948, and February 4, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused a number of tablets of the drugs to be removed from the bottles in which they had been shipped, to be repacked into boxes, small bottles, and envelopes, and to be sold to various persons without a prescription, which acts of the defendants resulted in the repackaged tablets being misbranded. Portions of the repackaged tablets were labeled in part "A. G. Crawford Pharmacies * * * Dexedrine Sulfate 5 mg." "Dexedrine Contents 5 mg. Packed by A. G. Crawford Pharmacies," "A. G. Crawford Pharmacies," or "Benzedrine 50 mg."

The containers involved in one sale of the *Dexedrine Sulfate Tablets* and in one sale of the *Benzedrine Sulfate Tablets* were unlabeled.

NATURE OF CHARGE: Adulteration, Section 501 (c), (1 lot of *Benzedrine Sulfate Tablets*) the strength of the tablets differed from that which they purported and were represented to possess since each tablet was represented to contain 50 milligrams of Benzedrine, whereas each tablet contained less than 50 milligrams of Benzedrine.

Misbranding, Section 502 (b) (2), the repackaged drugs failed to bear labels containing an accurate statement of the quantity of the contents; Section 502 (f) (1), the articles failed to bear labeling containing adequate directions for use; Section 502 (b) (1), (2 lots of *Benzedrine Sulfate Tablets* and 1 lot of *Dexedrine Sulfate Tablets*) the articles failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (e) (1), (1 lot of *Dexedrine Sulfate Tablets* and 2 lots of *Benzedrine Sulfate Tablets*) the repackaged tablets failed to bear the common or usual name of the drugs; and, Section 502 (a), (1 lot of *Benzedrine Sulfate Tablets*) the label statement "Benzedrine 50 mg." was false and misleading since the tablets contained less than 50 milligrams of Benzedrine.

DISPOSITION: October 3, 1949. Pleas of nolo contendere having been entered, the defendants were placed on probation for 1 year.

3042. Misbranding of thyroid tablets, phenobarbital tablets, sodium pentobarbital capsules, and Benzedrine Sulfate Tablets. U. S. v. Warren U. Rice (Rice Drug Store). Plea of guilty. Defendant fined \$750 and placed on probation for 1 year. (F. D. C. No. 28114. Sample Nos. 60778-K, 60802-K, 60806-K, 60808-K, 60817-K, 60818-K.)

INFORMATION FILED: January 17, 1950, Eastern District of Illinois, against Warren U. Rice, trading as the Rice Drug Store, Centralia, Ill.

INTERSTATE SHIPMENT: Between November 18, 1947, and June 6, 1949, from the State of Missouri into the State of Illinois, of quantities of *thyroid tablets*, *phenobarbital tablets*, *sodium pentobarbital capsules*, and *Benzedrine Sulfate Tablets*.

ALLEGED VIOLATION: On or about June 2, 6, and 13, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be removed from the bottles in which they had been shipped, to be repacked into envelopes, and to be sold without a prescription; and the defendant caused also a quantity of *phenobarbital tablets* that were contained in the original bottle which was shipped in interstate commerce, to be sold without a prescription, which acts of the defendant resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (b) (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *sodium pentobarbital capsules*, the repackaged *phenobarbital tablets*, and the *phenobarbital tablets* sold in the original bottle, contained derivatives of barbituric acid, which derivatives had been found to be, and by regulations designated by the Administrator of the Federal Surcify Agency as, habit forming; and the labels failed to bear the name, and quantity or proportion of the derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *Benzedrine Sulfate Tablets* were not designated solely by a name recognized in an official compendium, and their labels failed to bear the common or usual name of the drug, namely, Benzedrine Sulfate; and, Section 502 (f) (1), the repackaged drugs and the *phenobarbital tablets* sold in the original bottle, bore no labeling containing directions for use.

DISPOSITION: January 31, 1950. A plea of guilty having been entered, the court imposed a fine of \$750 and placed the defendant on probation for 1 year.

3043. Misbranding of nembutal sodium capsules, seconal sodium capsules, and Benzedrine Sulfate Tablets. U. S. v. Charles H. Stagner (East Erwin Drug Co.). Plea of guilty. Fine, \$50. (F. D. C. No. 26749. Sample Nos. 23850-K, 23856-K, 23864-K, 23873-K, 23876-K, 53206-K, 53207-K.)

LABEL FILED: November 10, 1949, Eastern District of Texas, against Charles H. Stagner, trading and doing business as the East Erwin Drug Co., Tyler, Tex.

INTERSTATE SHIPMENT: The information alleged that the *seconal sodium capsules*, the *Benzedrine Sulfate Tablets*, and a portion of the *nembutal sodium capsules* had been shipped in interstate commerce between the approximate dates of April 12, 1948, and January 17, 1949, from North Chicago, Ill., Indianapolis, Ind., and Philadelphia, Pa., and that the remainder of the *nembutal sodium capsules* had been manufactured at North Chicago, Ill., and shipped in interstate commerce into the State of Texas.

ALLEGED VIOLATION: On or about January 12 and 28, February 11, and March 3 and 10, 1949, and while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be repackaged and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs bore no label containing the name or place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the repackaged drugs bore no label containing a statement of the quantity of the contents; and, Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use.

Further misbranding, Section 502 (d), the repackaged *seconal sodium capsules* and *nembutal sodium capsules* were drugs for use by man and contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, after investigation, found to be and by regulations designated as, habit forming; and the labels of the repackaged capsules failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (e) (1), the repackaged *Benzedrine Sulfate Tablets* bore no label containing the common or usual name of the drug, namely, Benzedrine Sulfate.

DISPOSITION: February 6, 1950. A plea of guilty having been entered, the court imposed a fine of \$50.

3044. Misbranding of Benadryl Capsules and Dexedrine Sulfate Tablets. U. S. v. Godt Brothers, William C. Godt, and Henry C. Godt. Pleas of nolo contendere. Defendants placed on probation for 1 year. (F. D. C. No. 26733. Sample Nos. 27038-K, 27317-K.)

INFORMATION FILED: September 6, 1949, Western District of Arkansas, against the Godt Brothers, a partnership, Kansas City, Mo., and William C. Godt and Henry C. Godt, partners.

INTERSTATE SHIPMENT: On or about August 10 and 16, 1948, from the States of Missouri and Pennsylvania into the State of Arkansas.

ALLEGED VIOLATION: On or about August 31 and September 10, 1948, and while the articles were being held for sale after shipment in interstate commerce, the defendants caused quantities of the articles to be repackaged and sold to various persons without a prescription, which acts of the defendants resulted in the repackaged articles being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged articles bore no label containing an accurate statement of the quantity of the contents; and, Section 502 (f) (1), they failed to bear labeling containing adequate directions for use.

DISPOSITION: September 30, 1949. Pleas of nolo contendere having been entered, the court placed the defendants on probation for 1 year.

3045. Misbranding of Colusa Natural Oil and Colusa Natural Oil Capsules. U. S. v. 21 Bottles, etc. (and 15 other seizure actions). (F. D. C. Nos. 12896, 13126, 13370, 13384, 13406, 13610, 14040, 14731, 14740, 14745, 14791, 14797, 19169. Sample Nos. 61588-F, 61589-F, 61591-F, 61592-F, 72461-F, 72462-F, 73969-F, 73971-F, 77664-F to 77671-F, incl., 78164-F, 78165-F, 79544-F, 79545-F, 79921-F, 87120-F, 87121-F, 89661-F, 89901-F, 89902-F, 92103-F, 92104-F, 92386-F, 92387-F, 56625-H, 56626-H.)

LIBELS FILED: Between July 7, 1944, and February 8, 1946, District of Columbia, Eastern, Middle, and Western Districts of Pennsylvania, Western District of

Texas, Southern District of Iowa, Western District of Missouri, District of Arizona, Western District of New York, Eastern District of Michigan, Western District of Tennessee, and District of New Hampshire.

ALLEGED SHIPMENT: Between the approximate dates of March 9, 1944, and December 10, 1945, by the Colusa Remedy Co., from Hollywood and Los Angeles, Calif.

PRODUCT: 1,028 2-fluid-ounce bottles and 213 4-fluid-ounce bottles of *Colusa Natural Oil* and 635 100-capsule boxes and 158 200-capsule boxes of *Colusa Natural Oil Capsules* and a number of circulars headed "Colusa Remedy Co. Field Headquarters Williams, California," at Washington, D. C., Chester, West Chester, Coatesville, Conshohocken, Chambersburg, and Pittsburgh, Pa., Waco and San Antonio, Tex., Marshalltown, Iowa, Springfield, Mo., Phoenix, Ariz., Corning, N. Y., Saginaw, Mich., Memphis, Tenn., and Nashua, N. H.

Examination showed that the products consisted of petroleum oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars described above, which accompanied the products other than those involved in the New Hampshire action, and the pictures of a man's back, two hands, and a leg before and after treatment, which were displayed in the circulars, were false and misleading. The statements and pictures represented and suggested that the articles would be efficacious in the treatment of psoriasis, eczema, leg ulcers, itch, and athlete's foot. The articles when used alone or in combination with each other would not be efficacious for such conditions.

Further misbranding, Section 502 (f) (1), the labels of the articles involved in the New Hampshire action failed to bear adequate directions for use in the treatment of skin diseases, psoriasis, leg ulcers, and eczema, which were the conditions for which the articles were offered in advertising disseminated and sponsored by, and on behalf of, the packer.

DISPOSITION: The Colusa Remedy Co. appeared as claimant in each of the above-mentioned libel actions, and upon petition by the claimant, the libel actions were consolidated for trial in the Western District of Texas. On July 22, 1946, the claimant filed a motion to dismiss the libels, and on August 18, 1947, after consideration of the briefs of the parties, the court entered an order overruling and denying the motion to dismiss. An answer was filed also on behalf of the claimant, denying that the products were misbranded by the circulars and denying that the circulars constituted labeling. Thereafter a stipulation was entered into by the parties, which provided that final determination of the issue of misbranding in certain cases in the Northern District of Iowa (see notice of judgment on drugs and devices, No. 2922) should be applicable and decisive on the issue of misbranding in the instant cases, and that if in the Iowa cases, decrees of condemnation were finally entered, based on findings that the products seized therein were misbranded, then a decree of condemnation may be entered in the instant cases. In accordance with such stipulation, and in view of the decision reached in the Iowa cases, providing for condemnation of the products there involved, the court entered a decree in the instant cases, providing for condemnation and destruction of the products.

3046. Misbranding of vitamin and mineral tablets. U. S. v. 45 Bottles * * *.
(F. D. C. No. 28254. Sample No. 13697-K.)

LIBEL FILED: October 31, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 11, 1949, from Los Angeles, Calif.

PRODUCT: 45 60-tablet bottles of *vitamin and mineral tablets*. The product was offered "to give power" during lectures delivered by Thomas Gaines in

Philadelphia, Pa., and "for an aid to the preservation of adequate hearing and eyesight" in a mimeographed book entitled "Why Be Deaf" and "as a preventative of sight impairment" in a book entitled "Vitalic Breathing," which books were being sold by Thomas Gaines during his lectures.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: February 2, 1950. Default decree of condemnation. The court ordered that the product be delivered to a local hospital.

3047. Misbranding of mineral oil. U. S. v. 73 Bottles, etc. (F. D. C. No. 27187. Sample No. 44645-K.)

LIBEL FILED: May 7, 1949, District of Minnesota.

ALLEGED SHIPMENT: On or about January 24, 1949, from Petrolia, Pa.

PRODUCT: *Mineral oil.* 73 1-pint bottles, 29 ½-gallon bottles, 18 1-gallon bottles, and 92 1-quart bottles at Minneapolis, Minn. The product had been repackaged after shipment in interstate commerce and labeled with labels furnished by the Milton Ray Co., Minneapolis, Minn.

LABEL, IN PART: "Dr. Ray Brand Extra Heavy Mineral Oil U. S. P. Heavy * * * Distributed by Milton Ray Company, Minneapolis, Minn."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "safe for expectant mothers" was false and misleading since *mineral oil* may not be used without risk by pregnant women since it predisposes to hemorrhagic disease of the newborn; and, Section 502 (f) (2), the article failed to bear such adequate warnings against use by children where its use may be dangerous to health and against unsafe dosage and methods and duration of administration, in such manner and form as are necessary for the protection of users since its labeling failed to warn that the article should not be taken at any time other than bedtime or administered to infants except on advice of a physician. The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: On December 5, 1949, a default decree was entered, providing for destruction of the product unless given to charitable institutions. The United States marshal was informed that the product should be given to a charitable institution, such as a hospital which would have doctors and nurses qualified to administer the product, and that such institution should be informed concerning the charges of misbranding against the product. The product was delivered to a Minneapolis hospital.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3048. Adulteration of orris root. U. S. v. 67 Bags * * *. (F. D. C. No. 28290. Sample No. 10073-K.)

LIBEL FILED: November 21, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about October 25, 1948, from Leghorn, Italy.

PRODUCT: 67 164-pound bags of *orris root* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by the reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 15, 1949. Wessel, Duval & Co., Inc., New York, N. Y., claimant having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for fumigation, cracking, brushing, and sifting, or otherwise treating, so as to eliminate and destroy the objectionable portions and thereby bring the product into compliance with the law, under the provision of the Federal Security Agency. The reconditioning operations were completed on or about March 9, 1950, and resulted in the destruction of 1,628 pounds of the product as unfit.

3049. Adulteration of angelica seed. U. S. v. 17 Bags * * *. (F. D. C. No. 28062. Sample No. 56519-K.)

LIBEL FILED: On or about October 24, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about July 1, 1946, from Belgium.

PRODUCT: 17 150-pound bags of *angelica seed* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects and rodent excreta. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 29, 1949. The Meer Corp., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for segregation and destruction of the unfit portion, under the supervision of the Federal Security Agency. A total of 233 pounds of the product was found unfit and was destroyed, and the remainder of the product under seizure, consisting of 2,315 pounds, was found fit and was released on or about April 7, 1950.

3050. Adulteration of quince seed. U. S. v. 2,000 Pounds * * *. (F. D. C. No. 28063. Sample No. 57123-K.)

LIBEL FILED: October 21, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about July 1, 1949, from Iran.

PRODUCT: 2,000 pounds of *quince seed* in 8 drums and 1 bag at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 8, 1949. The Meer Corp., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for segregation and destruction of the unfit portion, under the supervision of the Federal Security Agency. The segregation operations were completed on or about April 7, 1950. Of the total of 1,503 pounds of the product which had been seized, 219 pounds were found unfit and were destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3051. Adulteration and misbranding of nembutal suppositories. U. S. v. Abbott Laboratories. Plea of nolo contendere. Fine of \$1,000, plus costs. (F. D. C. No. 26699. Sample Nos. 296-K, 692-K, 15960-K, 32034-K, 34101-K, 34102-K, 37091-K.)

INFORMATION FILED: July 12, 1949, Northern District of Illinois, against the Abbott Laboratories, a corporation, North Chicago, Ill.

*See also No. 3041.

ALLEGED SHIPMENT: Between the approximate dates of October 8, 1946, and June 10, 1947, from the State of Illinois into the States of Georgia, Indiana, California, and Washington.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since each suppository of the article purported and was represented to contain one grain of pentobarbital sodium, whereas some of the suppositories contained less than one grain of pentobarbital sodium and some of the suppositories contained more than one grain of pentobarbital sodium.

Misbranding, Section 502 (a), the label statement "Each suppository contains: * * * Pentobarbital Sodium * * * 1 gr." was false and misleading.

DISPOSITION: October 11, 1949. A plea of nolo contendere having been entered, the court imposed a fine of \$1,000, plus costs.

3052. Adulteration of physiological salt solution. U. S. v. 80 Vials * * *.
(F. D. C. No. 27695. Sample No. 53864-K.)

LIBEL FILED: August 18, 1949, Southern District of Alabama.

ALLEGED SHIPMENT: On or about July 12, 1949, by the Hyland Laboratories, from Los Angeles, Calif.

PRODUCT: 80 50-cc. vials of *physiological salt solution*, at Mobile, Ala. The form in which the product was packaged was that normally employed for drugs intended for parenteral administration (by injection), and the United States Pharmacopoeia provides that injections must be substantially free of undissolved material.

LABEL, IN PART: "Physiological Salt Solution (Isotonic Solution Of Sodium Chloride U. S. P.)."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Sterile Isotonic Solution of Sodium Chloride for Parental Use," a drug the name of which is recognized in the United States Pharmacopoeia, and official compendium, and its quality and purity fell below the official standard since it was contaminated with undissolved material.

DISPOSITION: October 26, 1949. Default decree of condemnation and destruction.

3053. Adulteration of prophylactics. U. S. v. 6 Cartons * * *. (F. D. C. No. 28472. Sample Nos. 63849-K to 63852-K, incl., 63854-K.)

LIBEL FILED: On or about December 9, 1949, Northern District of Georgia.

ALLEGED SHIPMENT: On or about June 1 and November 16, 1949, by the Klingfast Rubber Co., from Akron, Ohio.

PRODUCT: 6 cartons, each containing 29 gross, of short-type *prophylactics* at Atlanta, Ga. Examination of samples showed that 10.2 percent were defective in that they contained holes.

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

DISPOSITION: February 7, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS**DRUGS FOR HUMAN USE***

- 3054. Misbranding of Prostall.** U. S. v. Douglas Laboratories, Inc., and Edward Y. Domina. Pleas of nolo contendere. Fine of \$1 against corporation; individual placed on probation for 2 years. (F. D. C. No. 23257. Sample No. 63119-H.)

INFORMATION FILED: August 4, 1948, District of Massachusetts, against Douglas Laboratories, Inc., Boston, Mass., and Edward Y. Domina, president of the corporation.

ALLEGED SHIPMENT: On or about February 3, 1947, from the State of Massachusetts into the State of California.

PRODUCT: Analysis showed that the product consisted of gelatin capsules containing glutamic acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, which included a booklet entitled "The Story of Prostall," were false and misleading. The statements represented and suggested that the article would be effective to relieve the symptoms of prostate hypertrophy, whereas the article would not be effective for such purpose.

DISPOSITION: March 10, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$1 against the corporation and placed the individual on probation for 2 years on the condition that during such period he should not send through the mail or ship in interstate commerce the drug known as "Prostall" or any other drug of the same character for which the same claims were made.

- 3055. Misbranding of Improved Min-E-Vita.** U. S. v. Helios Foods, Inc., and Harry H. Grahm (Min-E-Vita Products Co.). Pleas of guilty. Fine of \$250 against the defendants jointly. (F. D. C. No. 25623. Sample Nos. 47745-H, 48261-H, 15932-K.)

INFORMATION FILED: January 16, 1950, Northern District of Illinois, against Harry H. Grahm, trading as the Min-E-Vita Products Co., Chicago, Ill., and against Helios Foods, Inc., Chicago, Ill., and Harry H. Grahm, president of the corporation.

ALLEGED SHIPMENT: On or about April 8, 1948, by Harry H. Grahm, trading as the Min-E-Vita Products Co., from the State of Illinois into the State of Michigan, and on or about September 25 and November 21, 1946, by Helios Foods, Inc., and Harry H. Grahm, president, from the State of Illinois into the State of Colorado.

LABEL, IN PART: "Improved Min-E-Vita A Unit Combination of Minerals and Vitamins * * * Contains * * * only the essential elements required in the normal human body. Calcium Potassium Phosphorus, Aluminum Iron-Sodium Copper-Iodine Magnesium Manganese * * * Each Capsule Contains Not Less Than: Vitamin A — 5000 U. S. P. Units Vitamin B₁ — 333 U. S. P. Units Vitamin C — 600 U. S. P. Units Vitamin D — 500 U. S. P. Units, Vitamin B₂-G — 1000 Gammas — Riboflavin Vitamin E — 2 Minims Wheat Germ Oil—Plus—10 Milligrams Calcium Pantothenate."

*See also No. 3041, 3045, 3047, 3051.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article, which included leaflets entitled "Reduce to Normal" and "Persons Who Are Obese," booklets entitled "Min-E-Vita versus Obesity," and "Helios Formula Min-E-Vita a Valued Agent," and a letter addressed to the consignee of one of the shipments, were false and misleading. The statements represented and suggested that the article would be efficacious in the treatment of border-line anemia, cancer, graying of the hair, wrinkles, colds, hay fever, asthma, pimples, acne, eczema, hyperacidity, acidosis, arthritis, general debility, dysmenorrhea, insomnia, nervous disorders, waning sexual vigor, brittle nails, diabetes, high blood pressure, kidney disorders, heart disease, degenerative conditions, digestive disorders, and sick headache; that the article would insure buoyant health, intensive vitality, and a good complexion; and that it would reduce weight to normal, maintain a positive nutritional balance, build resistance to disease, and prevent premature old age. The article would not be efficacious for such purposes.

Further misbranding, Section 502 (a), (portion of article) the label statement "Each capsule contains not less than: Vitamin B₁ — 333 U. S. P. Units Vitamin C — 600 U. S. P. Units" was false and misleading since one shipment of the article contained smaller amounts of vitamins B₁ and C than declared.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: March 22, 1950. Pleas of guilty having been entered, the court imposed a fine of \$250 against the defendants jointly.

3056. Misbranding of wheat germ oil capsules. U. S. v. 3 Bottles, etc. (F. D. C. No. 28006. Sample No. 13815-K.)

LIBEL FILED: September 27, 1949, Eastern District of Pennsylvania; amended libel filed on or about November 2, 1949.

ALLEGED SHIPMENT: On or about August 22 and September 16, 1949, from New York, N. Y.

PRODUCT: 3 500-capsule bottles and 66 90-capsule bottles of *wheat germ oil capsules* at Ivyland, Pa., in the possession of the Great Valley Mills, together with a number of leaflets entitled "What the Miracle of Wheat Germ means to you and your family" and a number of price lists. The leaflets and price lists were printed locally for the consignee.

Examination showed that the product was wheat germ oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the price lists and leaflets were false and misleading since the article when used as directed was not effective for the purposes stated and implied. The statements represented and suggested that the article when used as directed was effective to prevent and correct heart disease, infections, loss of vitality, eye troubles, sinusitis, glandular disorders of the mouth and throat, kidney and bladder disorders, poor appetite, digestive disturbances, constipation, loss of weight, nervous disorders, sterility in males, birth of paralytic children, and premature old age. The article was misbranded while held for sale after shipment in interstate commerce.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 15947.

DISPOSITION: December 12, 1949. Default decree of condemnation and destruction.

3057. Misbranding of Ruko Aromatic Iodine Bath and Ruko Double Strength Pine Needle Bath. U. S. v. 12 Bottles, etc. (F. D. C. No. 28026. Sample Nos. 42932-K, 42933-K.)

LIBELS FILED: October 28, 1949, Northern District of Illinois; amended libels filed on November 8 and December 23, 1949.

ALLEGED SHIPMENT: Between the approximate dates of April 20, 1947, and September 23, 1949, by the Ruko Chemical Co., from Kew Gardens, N. Y.

PRODUCT: 12 1-pound bottles of *Ruko Aromatic Iodine Bath* and 17 1-pound bottles of *Ruko Double Strength Pine Needle Bath* at Chicago, Ill., together with a number of post cards entitled "Ruko Products."

Analysis disclosed that the *Ruko Aromatic Iodine Bath* consisted of a powder mixture containing sodium carbonate, sulfur, sodium sulfate, borax, and potassium iodide, scented with pine needle oil; and that the *Ruko Double Strength Pine Needle Bath* consisted of a powder mixture containing sodium carbonate, sodium sulfate, borax, and pine needle oil.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the articles were false and misleading since the articles were not effective in the treatment of the conditions stated and implied: (*Ruko Aromatic Iodine Bath*) "Ind: In muscular and neuritic pains, high blood pressure and some cases of rheumatic arthritis. Reducing Treatments"; (*Ruko Double Strength Pine Needle Bath*) "Ind: General nervousness, insomnia, Graves' disease, anxiety, neurasthenia and heart neurosis" and "Soothing to the nerves."

DISPOSITION: April 13, 1950. Default decree of condemnation and destruction.

3058. Misbranding of Sinuothermic device. U. S. v. 16 Devices known as Sinuothermic and a number of leaflets. Tried to the court. Decree of condemnation and destruction. Judgment reversed upon appeal to court of appeals; judgment of court of appeals reversed by Supreme Court. (F. D. C. No. 17606. Sample No. 14003.-H.)

LIBEL FILED: September 27, 1945, Southern District of Ohio; amended libel filed on or about October 2, 1945; second amended libel filed on or about January 9, 1947, in the Northern District of Florida, after removal of the case to that district for trial.

ALLEGED SHIPMENT: Between the approximate dates of June 1, 1945, and September 28, 1945, by Fred Urbuteit, from Tampa, Fla.

PRODUCT: 16 devices known as *Sinuothermic*, located at Cincinnati, Ohio, together with a number of leaflets entitled "The Road to Health."

The devices involved were of two externally different types, one of which was called the master unit and the other the treating unit. The master unit consisted of a wooden cabinet containing electrical parts, including three voltmeters, a milliamperemeter, a light switch, a potentiometer, a step-down transformer, and wires, and pad electrodes which were pieces of flat metal padded with wool felt on one side and sheet rubber on the other. The treating unit consisted of a wooden box containing the same electrical parts except for the voltmeters and milliamperemeter. The electrodes were intended to be applied to the area of the body in which pain existed, and the current was to be passed through the body by turning the potentiometer control to give a tingling sensation. The devices did not alter the form of the electrical current delivered from the ordinary wall socket to any other form of current, but merely stepped down the voltage to a maximum value of 60 volts.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets were false and misleading since they represented and suggested that the devices would be effective in the diagnosis, cure, mitigation, treatment, and prevention of painful breathing, internal growths, arthritis, hardening of the arteries, heart disease, paralysis, cancer, diabetes, tuberculosis, prostate trouble, deficient hearing, hay fever, infantile paralysis, glandular and nervous disorders, tumors of the bladder and uterus, uterine hemorrhage, diseased kidneys, nervousness, nerve disorders, peritonitis, low blood pressure, ulcerated colon, appendicitis, obstructed colon, and menstrual dysfunction, or discomfort associated with menstruation. The devices would not be effective for those purposes.

DISPOSITION: Fred Urbuteit, Tampa, Fla., and J. J. H. Kelsch, Cincinnati, Ohio, claimants, having denied that the devices were misbranded as charged in the libel, and the case having been removed to the Northern District of Florida on or about September 20, 1946, came on for trial before the court without a jury on January 23, 1947. The taking of testimony was concluded on January 24, 1947. On January 27, 1947, the court handed down the findings of fact and conclusions of law that the devices were misbranded within the meaning of the law and entered a decree condemning the devices and ordering their destruction.

A motion for a new trial filed by the claimant, Fred Urbuteit, was denied on February 6, 1947, and on April 21, 1947, upon motion of the Government, judgment taxing costs was entered against the claimants in the amount of \$1,150.64. On May 1, 1947, a notice of appeal to the United States Court of Appeals for the Fifth Circuit was filed by Fred Urbuteit. The matter came on for argument before that court on October 22, 1947, and on November 7, 1947, the following opinion was handed down:

SIBLEY, *Circuit Judge*: "Under the Food, Drug and Cosmetic Act of 1938, Section 304 (21 U. S. C. A. § 334), sixteen electrical machines or devices were seized for condemnation in Ohio as having been misbranded when shipped in interstate commerce from Tampa, Florida, by appellant Fred Urbuteit to J. J. H. Kelsch at Cincinnati. The misbranding was alleged to consist of printed matter which accompanied them while in interstate commerce which was false and misleading in that it represented the machines as having therapeutic value in the diagnosis and treatment of stated diseases of man, whereas the devices were not effective for such purposes. Kelsch claimed six of them as his, and Urbuteit claimed ten of them as belonging to himself but rented to Kelsch. After trial, the case by consent having been transferred to Florida, a judgment of condemnation and destruction was rendered, with recovery of some \$1,150.64 costs. Urbuteit appeals.

"The claims admit that six machines were sold by Urbuteit to Kelsch and shipped in interstate commerce as alleged and that the ten others were rented and shipped to Kelsch by express, and that the printed matter was at the request of Kelsch sent by Urbuteit to Kelsch by parcel post; but deny that it was a labeling of the machines or accompanied them, and deny that its statements are false and misleading. The testimony, in great volume, related mostly to the falsity of the statements. We consider first, however, whether there was a misbranding proven under the Act.

"Section 301 (a) (c) (21 U. S. C. A. § 331 (a) (c)) prohibits the introduction into and the receipt in interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded, and Section 304 (a) (21 U. S. C. A. § 334 (a)) provides for seizure and condemnation of such. It is not denied that these machines were devices within the Act. By Section 502 (a) (21 U. S. C. A. § 352 (a)) a drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular. A definition in Section 201 (21 U. S. C. A. § 321), which is the dictionary of the Act, is: '(m) The term labeling means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' The last three quoted words are critical here. They make the

term 'labeling' broader than 'label' as defined in paragraph (k), which includes only what is 'displayed on the immediate container' of an article. How much broader? In *United States vs. Research Laboratories*, 126 F. (2) 42, it was held that printed matter which did not travel with the article but was sent by the same shipper to the same consignee and received at the same time for use in connection with the article, 'accompanied' it. But the same court in *Alberty vs. United States*, 159 Fed. (2) 278, refused so to hold when the printed matter and the article were shipped two months apart and not simultaneously. Accepting those decisions as sound, the latter controls here. It is shown that machines valued at \$4,300 were shipped July 25, 1945; value \$1,200 August 14; value \$800 August 18; and value \$1,200 Sept. 21. Kelsch testified that he had an understanding with Urbuteit that he would mail him some printed matter before he finally contracted for the machines, and that the matter was received about September, after the machines were delivered. It was found by the inspectors in Kelsch's consultation room, the machines being all in other rooms, on Sept. 5. The claim alleges the printed matter was mailed Sept. 1. It did not 'accompany' in any fair sense either shipment. Both the amended libel and the second amended libel allege that the false leaflets 'accompanied said articles of device when said articles were introduced into and while said articles of device were in interstate commerce.' This is the exact language of Section 304 (a), the forfeiture provision of the statute, but it is shown not to be true of any shipment. The first three shipments went forward and were received by Kelsch, and put to work in his medical practice several weeks before any leaflets were sent. They did not accompany any of the devices while they were in interstate commerce. The last shipment went forward three weeks behind the leaflets, and was not accompanied by them. Accompany means to go along with. In a criminal and forfeiture statute the meaning cannot be stretched.

"It may be doubted that the printed matter is in its nature a labeling for the machines. It looks like a small newspaper, entitled 'The Road to Health, By Dr. Fred Urbuteit. Every subject pertaining to Health, Doctoring and Nursing is being taught at the College of Sinuothermic Institute, Inc., 307 West Euclid Ave., Tampa, Florida.' To the left of this heading is a picture of Dr. Fred Urbuteit, President of Sinuothermic Institute, Inc., and to the right an attractive picture of the Institute and its grounds. Fifteen columns of fine print are below, consisting of testimonials and case histories of patients who had been treated at the Institute by Dr. Urbuteit, with unstinted praise of both. The Sinuothermic machine is mentioned and praised as an instrument of diagnosis and treatment, but there is no description or picture of the machine or any explanation of its operation, or any suggestion that it is for sale. The whole thing appears to be an advertisement for the Institute and Dr. Urbuteit, rather than something to accompany machines. Dr. Urbuteit is licensed as a practitioner of naturopathy in Florida. Dr. Kelsch is a chiropractor in Ohio. Dr. Kelsch became interested in Dr. Urbuteit's work and took a three weeks' course at the Institute, and on the strength of it, on returning to Ohio, bought some of the machines and rented others. He re-rented one to a patient to use at home, and sold one to another patient who moved to another State. The literature apparently was intended to advertise himself as following the methods of Dr. Urbuteit, rather than to explain or sell machines. Whether we ought to hold it a labeling of these machines if shipped simultaneously with them may be doubted. But if it could be called labeling, it is not proved by the present skimpy evidence that it accompanied the machines or any of them while they were in interstate commerce.

"Dr. Urbuteit vigorously contended that all he had said in 'The Road to Health' was true. He offered in his claim, since no employee of the United States had any actual knowledge of his machine and only a few practitioners whom he had instructed, to conduct a series of tests of it in cooperation with practitioners of medicine, osteopathy, chiropractic, and naturopathy approved by the court, on persons preferably before treated by medical practitioners without success, they to be examined before and after the test by physicians appointed by the court, during such period as the court should fix, their findings of the results to be evidence in the case. This was not done. Dr. Urbuteit at least seems convinced of the efficacy of his machine. He testifies that he was himself a suffering and distorted victim of arthritis deformans, and was helped to a degree which he described in detail, and exhibited his diseased joints to the court. He describes the construction of his machine, claims peculiarities in the winding of the electrical transformers in it which experi-

mentally he found to produce currents peculiarly affected by diseased or congested bodily tissues, which when measured indicate where the trouble is, although often remote from the pain and other symptoms, and that it aided in locating the cause of trouble; and that a modified type of machine also was useful in treating many ailments. He testified in detail as to each case mentioned in 'The Road to Health.' He had thirty of his patients present whom he offered as witnesses to the benefits they had received, many of them being those mentioned in 'The Road to Health.' The judge refused to hear them, on the ground that being laymen they could not testify what was the matter with them and consequently could not say, what they were relieved from, and that the diagnoses testified to by Dr. Urbuteit could not be accepted because he rested them on the use of his machine which the Government's witnesses, who were men of high standing in medicine and in the electrical arts, had testified could not do what Dr. Urbuteit claimed. These rulings were error. One was based on the idea that Dr. Urbuteit had made his diagnoses solely on the indications of the machine. But his testimony as a whole was that he used all known methods of diagnosis, that the machine did not indicate any particular disease but only located the spot where the abnormal tissue was, and it was then a matter of judgment as to what the disease was. He only claimed the machine to be an aid in diagnosing. The patients themselves could certainly know whether their external symptoms abated and their pains ceased. Urbuteit, being a licensed doctor of some twenty years practice, could express expert opinions. The judge might, after hearing all the evidence, prefer the expert opinions of the Government witnesses to those of Dr. Urbuteit, even as against the facts to which he and his witnesses might swear, but he should have heard all the competent testimony before making up his mind. The most eminent physicians and scientists have in the past erred in their opinions, and opinions generally must yield to well proven contrary facts. The case ought to have been more fully tried.

"The judgment is reversed and the cause remanded for further proceedings consistent with this opinion."

A petition for a writ of certiorari was filed on behalf of the Government in the United States Supreme Court on February 6, 1948, and was granted on April 19, 1948. On November 22, 1948, after consideration of the briefs and arguments of counsel, the Supreme Court handed down the following opinion:

MR. JUSTICE DOUGLAS:

"The United States filed a libel under the Federal Food, Drug, and Cosmetic Act (52 Stat. 1044, 21 U. S. C. § 334), seeking seizure of 16 machines labeled 'Sinuothermic.' The libel alleged that the device was misbranded within the meaning of the Act (52 Stat. 1050, 21 U. S. C. § 352 (a)) in that representations in a leaflet entitled 'Road to Health' relative to the curative and therapeutic powers of the device in the diagnosis, cure, mitigation, treatment and prevention of disease were false and misleading. It charged that the leaflet had accompanied the device in interstate commerce.

"Respondent, Fred Urbuteit, appeared as claimant of several of the devices. He admitted that the devices and leaflets had been shipped in interstate commerce, but denied that they were shipped together or that they were related to each other. He also denied that the statements made in the leaflet were false or misleading. The case was tried without a jury and the articles were ordered condemned. The judgment was reversed by the Court of Appeals. 164 F. 2d 245. The case is here on certiorari to resolve the conflict between it and *Kordel v. United States*.

"Respondent Urbuteit terms himself a naturopathic physician and conducts the Sinuothermic Institute in Tampa, Florida. The machines against which the libel was filed are electrical devices allegedly aiding in the diagnosis and cure of various disease and physical disorders such as cancer, diabetes, tuberculosis, arthritis, and paralysis. The alleged cures effected through its use are described in the allegedly false and misleading leaflet, 'The Road to Health,' published by Urbuteit and distributed for use with the machines.

"Urbuteit shipped from Florida a number of these machines to one Kelsch, a former pupil of his who lives in Ohio. Kelsch used these machines in treating his patients and, though he did not receive them as a merchant, he sold some to patients. As part of this transaction Urbuteit contracted to furnish Kelsch with a supply of leaflets, which were sent from Florida to Ohio at a

different time than when the machines were forwarded. Kelsch used the leaflets to explain the machines to his patients.

"The leaflets seem to have followed the shipment of the machines. But as *Kordel v. United States* holds, that is immaterial where the advertising matter that was sent was designed to serve and did in fact serve the purposes of labeling. This machine bore only the words, 'U. S. Patent Sinuothermic Trade Mark.' It was the leaflets that explained the usefulness of the device in the diagnosis, treatment, and cure of various diseases. Measured by functional standards, as § 201 (m) (2) of the Act permits, these leaflets constituted one of the types of labeling which the Act condemns.

"The power to condemn is contained in § 304 (a) and is confined to articles 'adulterated or misbranded when introduced into or while in interstate commerce.'¹ We do not, however, read that provision as requiring the advertising matter to travel with the machine. The reasons of policy which argue against that in the case of criminal prosecutions under § 303 are equally forcible when we come to libels under § 304 (a). Moreover, the common sense of the matter is to view the interstate transaction in its entirety—the purpose of the advertising and its actual use. In this case it is plain to us that the movements of machines and leaflets in interstate commerce were a single interrelated activity, not separate or isolated ones. The Act is not concerned with the purification of the stream of commerce in the abstract. The problem is a practical one of consumer protection, not dialectics. The fact that the false literature leaves in a separate mail does not save the article from being misbranded. Where by functional standards the two transactions are integrated, the requirements of § 304 (a) are satisfied, though the mailings or shipment are at different times.

"The Court of Appeals held that certain evidence tendered by Urbuteit as to the therapeutic or curative value of the machines had been erroneously excluded at the trial, a ruling that we are not inclined to disturb. Petitioner claims, however, that the error was not prejudicial. The argument is that since the evidence of the false and misleading character of the advertising as respects the diagnostic capabilities of the machines was overwhelming, that false representation was adequate to sustain the condemnation, though it be assumed that the therapeutic phase of the case was not established. We do not reach that question. Since the case must be remanded to the Court of Appeals, that question and any others that have survived will be open for consideration by it. *Reversed.*

"Mr. Justice Black, Mr. Justice Frankfurter, Mr. Justice Murphy, and Mr. Justice Jackson dissent for the reasons stated in their dissent in *Kordel v. United States*, No. 30, decided this day."

Upon remand of the case to the Court of Appeals for the Fifth Circuit, a motion was filed in that court on behalf of the Government to affirm the decree of condemnation of January 27, 1947, and on February 1, 1949, the court of appeals handed down the following decision:

SIBLEY, HUTCHESON, AND HOLMES, *Circuit Judges*: "Our judgment in this case, reported 164 Fed. (2) 245, was reversed in *United States vs. Fred Urbuteit*, . . . U. S. . . ., and the cause remanded to us for further proceedings in conformity with the opinion of the Supreme Court. The reversal was on the one point, that certain advertising matter shipped separately from any of the machines and held by us for that reason not to have 'accompanied' any of them might nevertheless constitute 'labeling,' if the movements of advertising and machines in interstate commerce were a single interrelated activity and not separate or isolated ones. There were four or five shipments of machines several weeks apart, and only one shipment of advertising. It does not appear whether there was a single interrelated activity in machines and advertising as to each shipment, or as to which shipments. That appears to be a question which should be further investigated.

"The Supreme Court did not disturb our former ruling that the district court should have heard all the evidence offered on the question of the falsity of the

¹ The relevant portion of this section reads as follows:

"Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce . . . shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found. . . ."

advertising. We adhere to that ruling. The judgment of the district court is accordingly reversed and the cause remanded for further proceedings in conformity with the opinion of the Supreme Court and with this opinion. *Judgment reversed.*"

Thereafter, the Government petitioned the Supreme Court for a writ of certiorari, and on May 2, 1949, the Supreme Court handed down the following decision:

"*PER CURIAM*: The question presented by this petition is whether the Court of Appeals followed our mandate on remand of the cause in 335 U. S. 355.

"The case when it was here earlier this Term appeared in the following posture:

"A condemnation proceeding was instituted by the United States under the Federal Food, Drug, and Cosmetic Act (52 Stat. 1044, 21 U. S. C. § 334). Sixteen machines with alleged diagnostic and curative capabilities had been shipped in interstate commerce. Leaflets describing the uses of the machine had been shipped at a separate time. The Court of Appeals had held that the separate shipments of the machines and leaflets precluded a conclusion that the leaflets had accompanied the device in interstate commerce, and therefore the transaction was outside the reach of the Act. We reversed the Court of Appeals and held that the separate shipment of the machines and leaflets constituted a single interrelated activity.

"On remand the Court of Appeals concluded that because there were several shipments of machines and a single shipment of advertising matter, it was not clear which shipments might be considered a single interrelated activity. Therefore, it remanded the case to the District Court for a determination of this fact.

"When the case was here before, we decided that the fact of separate shipments of machines and leaflets were immaterial. The controlling factors were whether the leaflets were designed for use with the machine and whether they were so used. Since the function of the leaflets and the purpose of their shipment were established, nothing more was needed to show that the movements of the machines and leaflets constituted a single interrelated activity. Moreover, the case is not complicated by shipments of machines and leaflets to different persons. One Kelsch was the recipient of both.

"On remand the Court of Appeals adhered to its former ruling that the District Court erroneously excluded evidence as to the therapeutic or curative value of the machines. When the case was here before we did not disturb that ruling. But we did leave to the Court of Appeals for consideration a further question—whether the evidence as respects the falsity of the diagnostic capabilities of the machine was adequate to sustain the condemnation even though error in exclusion of the other evidence were conceded. The United States is entitled to a hearing on that question.

"The petition for certiorari is granted and the judgment is *Reversed*."

Following the remanding of the case to the Court of Appeals for the Fifth Circuit, the Government renewed its motion that the decree of condemnation of January 27, 1947, be affirmed. This motion was granted on August 2, 1949, Circuit Judge Sibley dissenting with the following opinion:

SIBLEY, *Circuit Judge*: "My brethren feel compelled by the opinions of the Supreme Court in this case to grant the Government's motion to affirm the decree of the District Court forfeiting the sixteen electric machines seized as misbranded. The last mandate does not direct us to affirm. If it did, the full responsibility for a wrong decision would be on the Supreme Court. It remands the case to us for further proceedings in conformity with the opinions of the Supreme Court, and this remand requires us to exercise a judicial and not a ministerial function. To join in the affirmance would make me feel both foolish, and false to my judicial oath to support the Constitution of the United States which I think is being violated. This bold statement needs to be justified.

"The second amended libel describes the machines as 'numbered X8 and X10 of the so-called Master Type, the others bearing numbers T20, T23, (naming 14), of the so-called Treating Unit Type.' Dr. Kelsch filed a claim to the machines X8, X10, T20, T25, T26, and T32. Dr. Fred Urbuteit disclaimed any interest in these six, having sold them to Dr. Kelsch, but he filed a claim to the remaining ten T-type machines which he alleged he had rented to Dr. Kelsch. The evidence is clear that the ownership was as stated. It is also clear that the

Master Type machines alone have voltmeters and milliampere meters and dials for reading them, and that this type alone is used by the practitioner in diagnosing. The Treating Type machines are for use by patients and have nothing to do with diagnosing. Assuming the falsity of statements in the 'Road to Health' as to capacity to diagnose, these statements relate only to the diagnosing machines. The false statements as to successful treatment relate only to the Treating Type. The difference is like that between X-ray machines which take photographs for diagnosis and those which apply such rays to the patient in treatments. The district judge, in paragraph 3 of his findings of fact, distinguishes the two types of machine and their use; and in paragraph 5 he deals with the Master Type machines and their use in diagnosing, and concludes: 'The Master Machine therefore is incapable of diagnosing any diseased condition.' In paragraph 6 he turns to the question of therapeutic and curative effects and finds, on the incomplete evidence before him, that no such effect is or can be produced. He therefore condemned all the machines.

"Dr. Kelsch did not appeal his case. His 6 machines stand condemned, including both the X8 and X10 Master Type Machines. Urbuteit appealed, and his ten Treating Type rented machines alone are now before this court. No one has ever represented that the treating type machines were useful in diagnosing. The evidence as to usefulness in treatment has not been fully heard, thirty witnesses for Urbuteit being present and ready to testify, but excluded for a reason this court has held to be insufficient. It must be assumed, on this motion to affirm for false statements as to diagnosis only, that these ten machines are useful for treatment, the purpose for which they are intended. It therefore seems to me foolish to say that because Urbuteit sold two Master Type Machines to Kelsch which were mislabeled as to diagnostic powers, he forfeited also ten machines of another kind which he later rented and shipped to him.

"The skimpy but uncontradicted evidence as to the printed leaflets, 'The Road to Health,' is that before buying his first machines Dr. Kelsch asked Dr. Urbuteit to send him some copies, and some were sent by mail about September 1, 1945, and mailed out by Dr. Kelsch to some of his patients. Machines had been shipped July 25, August 14, and August 18, 1945. The last three were shipped September 21, 1945. It does not appear whether these shipments were on separate orders. The Supreme Court, without evidence or a finding by the district judge, has said they were a 'single interrelated activity' with the sending of the printed leaflets. I suppose that we are to understand that all re-orders of foods, drugs, cosmetics and devices are forfeited if the first lot be falsely labelled. This would be in keeping with the holding that these leaflets 'accompanied' any of these machines. They did not. The forfeiture of these devices, good or bad, would be impossible except for the Federal Food, Drug and Cosmetics Act, 21 U. S. C. A. Section 334, providing for forfeiting of 'Any . . . device that is misbranded . . . while in interstate commerce.' Misbranding includes false labeling. Section 321 (m) declares 'The term "labelling" means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' [*Emphasis added.*] The printed matter here is said to have accompanied these machines 'while in interstate commerce' because it was mailed to the same person several weeks after some of the machines were sent and several weeks before others. The only interstate commerce in which the machines ever were was their transportation from Florida to Ohio, in four separate express shipments. No machine was in interstate commerce except during its transportation. All but three had arrived and been delivered in Ohio from two weeks to six weeks before any printed matter was started. How could they be thereby 'misbranded' while in interstate commerce?

"'Accompany' is a plain English word wholly unambiguous. It was used by Congress to *define*, not to *be defined*. It defines not only a *forfeiture* but also a *crime*. What it means in forfeiting property it also means in forfeiting liberty in a criminal prosecution under the statute. All the dictionaries I have seen say it means 'to go along with.' They say also it is used in music, but who would think a pianist 'accompanies' a soloist, if he performs an hour before or after? I surely do not 'accompany' another on any trip if I either precede or follow by a space of weeks. The courts here are adding words to the definition made by Congress, and making it read 'accompany, or precede or follow in an inter-related activity.' And an 'interrelated activity' is badly in need of definition itself. To thus amend a plain statute is to legislate, and for the

courts to do it is to violate the very first sentence in our Constitution: 'All legislative powers herein granted shall be vested in the Congress of the United States which shall consist of a Senate and House of Representatives.' The courts have no right to alter a statutory definition; or otherwise try to make a tighter law than Congress has made. Sworn to uphold the Constitution, judges ought to be careful about engaging in judicial legislation. I can accomplish nothing here, but I feel bound to protest. I am not concerned so much about Dr. Urbuteit and his machines, which may be worthless or worse, but I am greatly concerned about unlawful perversion of the statutory law."

A petition for rehearing filed by the claimant, Fred Urbuteit, was denied on September 13, 1949, and the petition of this claimant to the Supreme Court for a writ of certiorari was denied on February 6, 1950. On April 21, 1950, upon motion of the Government, an order was entered by the United States District Court for the Northern District of Florida, directing that in lieu of destruction four of the devices be delivered to the Food and Drug Administration.

3059. Misbranding of Drown Radio Therapeutic Instrument. U. S. v. 1 Device, etc. (F. D. C. No. 28009. Sample No. 60624-K.)

LIBEL FILED: October 4, 1949, Northern District of Illinois.

ALLEGED SHIPMENT: The device and certain printed matter were transported by Edgar Rice on or about October 28, 1948, from Los Angeles, Calif., to Blue Island, Ill., and certain printed matter was shipped from Los Angeles, Calif., by the Drown Laboratories in May or June 1948, and on March 10 and April 28, 1949.

PRODUCT: 1 *Drown Radio Therapeutic Instrument* at Blue Island, Ill., together with a leaflet entitled "Drown Atlas," circulars entitled "The Drown Radio Diagnostic Therapeutic Photographic Instruments," and a diagnostic chart entitled "The Drown Radio Therapy."

Examination showed that the device was a closed box resembling a radio set, equipped with 15 dials, 3 terminal posts, and an ammeter or voltmeter.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the leaflets, circulars, and diagnostic chart were false and misleading since the device was not effective for the purposes or conditions stated or implied. The statements represented and suggested that the device was effective in forming healthy cells, measuring functions of the body, making blood counts and urinalyses, determining blood pressure, determining temperature, and diagnosing and treating diseases and abnormalities in any part of the body, including, but not limited to, kidney and bladder complications, adhesions, tipped uterus, extra kidneys, painful urination, paralysis, inability to talk, heart trouble, noises in the ear, constipation, pains in lower back, effects of scarlet fever, septicemia in left mastoid, headache, streptococcus, abscesses, loss of speech and memory, inability to digest food, vomiting bile, diseases of the glands, female organs, male organs, and blood, and colds and sore throat.

DISPOSITION: November 11, 1949. Default decree of condemnation. The court ordered that the device and the printed matter be released to the Food and Drug Administration.

DRUG FOR VETERINARY USE

3060. Misbranding of Smith's Preparation No. 1. U. S. v. Jennie L. Johnson (Nu Lac Yeaston Co.). Plea of nolo contendere. Fine of \$50, plus costs. (F. D. C. No. 28109. Sample No. 44928-K.)

INFORMATION FILED: January 4, 1950, Southern District of Iowa, against Jennie L. Johnson, trading as the Nu Lac Yeaston Co., Jefferson, Iowa.

ALLEGED SHIPMENT: On or about February 15, 1949, from the State of Iowa into the State of South Dakota.

PRODUCT: Analysis disclosed that the product consisted of copper sulfate 44.04 percent, magnesium sulfate 7.63 percent, potassium iodide 0.30 percent, and methylene blue 0.25 percent, and charcoal and plant material.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label and in order blanks accompanying the article were false and misleading. The statements represented and suggested that the article would be effective in the treatment of necro in hogs, whereas it would not be effective for such purpose.

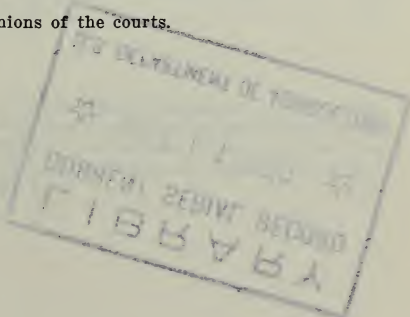
DISPOSITION: April 22, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$50, plus costs.

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PRODUCTS

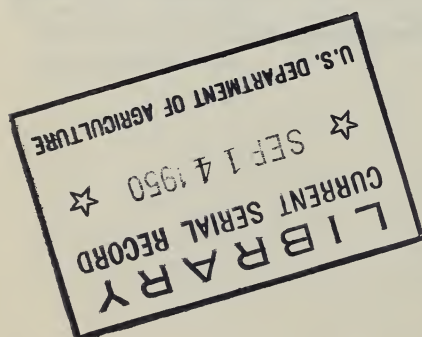
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¹ (3058) Seizure contested. Contains opinions of the courts.



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FEDERAL SECURITY AGENCY**FOOD AND DRUG ADMINISTRATION**

**NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3061-3080

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., August 16, 1950.

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*For presence of a habit-forming narcotic without warning statement, see Nos. 3064, 3065; omission of, or unsatisfactory, ingredients statements, Nos. 3062-3064, 3066; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3063-3066; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3063, 3064, 3066.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE
DIRECTIONS OR WARNING STATEMENTS

3061. Action to enjoin and restrain the interstate shipment of Colusa Natural Oil and Colusa Natural Oil Capsules. U. S. v. Chester Walker Colgrove (Colusa Remedy Co.), and Colusa Remedy Co., a corporation. Tried to the court; injunction granted. Action for violation of injunction tried to the court; verdict of guilty. Corporation fined \$5,000; individual fined \$4,000 and placed on probation for 5 years. Judgment affirmed on appeal. Petition for certiorari denied by United States Supreme Court. (Inj. No. 140.)

COMPLAINT FILED: November 20, 1946, Southern District of California, against Chester Walker Colgrove, trading as the Colusa Remedy Co., Los Angeles, Calif. The complaint alleged that the defendant had been and was then shipping in interstate commerce *Colusa Natural Oil* and *Colusa Natural Oil Capsules* which were misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labels of the articles failed to bear adequate directions for use in that the directions for use in the labeling were not adequate in any of the conditions for which the articles were recommended or suggested in their advertising sponsored by the defendant, the packager of the articles. The articles were held for sale to the public for medicine in the treatment of psoriasis, eczema, leg sores, leg ulcers, and athlete's foot.

PRAYER OF COMPLAINT: That a temporary restraining order issue, restraining the defendant from commission of the acts complained of; that pending final determination of the case, a preliminary injunction issue; and that after due proceedings, the preliminary injunction be made permanent.

DISPOSITION: On November 22, 1946, a temporary restraining order was issued against the defendant Colgrove, restraining him from introducing into interstate commerce the products known as *Colusa Natural Oil* and *Colusa Natural Oil Capsules*, until further order of the court. The temporary restraining order subsequently was dissolved, and the Colusa Remedy Co., a corporation, was added as a defendant in the action. The case came on for trial before the court on December 2, 1946. Upon the Government's motion for a preliminary injunction, and after consideration of the evidence submitted and the briefs of the parties, the court, on February 14, 1947, ordered that the defendants be enjoined pending determination of the action. On April 14, 1947, the court, with the consent of the defendants, entered a decree permanently enjoining the defendants from introducing *Colusa Natural Oil*, or any like product, into interstate commerce without a label containing adequate directions for the use of such product in the treatment of all conditions, ills, and diseases for which such product should be prescribed, recommended, and suggested in the advertising material disseminated or sponsored by or on behalf of the defendants, or either of them, which directions should include the quantity of the dose to be taken or applied in the treatment of each of such

conditions, ills, and diseases, as well as the frequency and duration of administration or application of such doses.

On October 3, 1947, an information was filed against both defendants, charging that they had made a number of shipments of *Colusa Natural Oil* and that the labels failed to bear adequate directions for use for certain conditions for which the drug was prescribed, recommended, and suggested in advertising material disseminated and sponsored by the defendants, in disregard of the requirements of the injunction. The matter came on for hearing before the court without a jury on or about December 19, 1947, and at the conclusion thereof, the court found the defendants guilty of contempt. On January 5, 1948, the court fined the Colusa Remedy Co. \$5,000 and Chester Walker Colgrove \$4,000, and sentenced the latter to two years in jail. The jail sentence was suspended, and the defendant was placed on probation for a period of five years, conditioned upon payment of the fine and compliance with all Federal, State, and local laws.

A notice of appeal to the United States Court of Appeals for the Ninth Circuit was filed by the defendants on January 13, 1948; and on August 8, 1949, after consideration of the briefs and arguments of counsel, the following opinion was handed down by that court:

HEALY, *Circuit Judge*: "This is an appeal from a judgment holding the appellants in criminal contempt of a preliminary and permanent injunction issued under 21 USCA Section 332 (a), a provision of the Federal Food, Drug and Cosmetic Act.

"The corporate appellant is controlled by the individual appellant Colgrove. For a number of years Colgrove has been marketing through this or other companies two products, Colusa Natural Oil and Colusa Natural Oil in capsules, and has advertised them on a national scale as remedies beneficial in the treatment of various skin diseases. His court experience in this respect is of significance. In a case decided in 1947, *United States v. 9 Bottles Colusa Natural Oil*, 78 F. Supp. 721, there were findings that the products are composed of crude petroleum oil and are of no value in the treatment of skin affections; and that their use in some circumstances may even be harmful. Numerous actions have been resorted to by the government in all parts of the country for the condemnation of the products because of the asserted illegal introduction of them in commerce, in most of which proceedings judgments for the complainant were taken by default.¹ In 1942 Colgrove and a corporation he controlled were convicted in the district court for the Northern District of California of violating the Act by the interstate shipment of misbranded drugs.²

"In 1945 appellants changed the labeling of the Colusa Oil preparations so that the labels failed to mention any maladies for which the drugs were recommended. However, they then proclaimed the worth of the products in the treatment of specified ailments extensively in newspaper advertisements. Early in 1947 the United States sought an injunction in the court below restraining the shipment of the products in interstate commerce without a label containing adequate directions for their use in the treatment of all conditions for which they were prescribed, recommended and suggested in the advertising material. The action was predicated on 21 USCA Section 352 (f) (1), which provides that a drug or device shall be deemed to be misbranded unless its labeling bears adequate directions for use.³ A preliminary injunction was

¹ Consult Federal Security Agency publications, "Notices of judgment under the Federal Food, Drug and Cosmetic Act, Nos. 1383 and 2087," dated April 1946 and December 1947, respectively.

² The conviction was set aside by this court because of rulings on evidence (136 F. 2d 868), and on remand there was a plea of *nolo contendere* and sentences of fine and imprisonment were imposed.

³ Interpretative regulations of the Federal Security Administrator, promulgated pursuant to 21 USCA Section 371 (a), provide that directions for use may be inadequate by reason of omission, in whole or in part, of directions for use "in all conditions for which such drug or device is prescribed, recommended, or suggested in its labeling, or in its advertising disseminated or sponsored by or on behalf of its manufacturer or packer. . . ." Section 2.106 (a), Title 21 Code of Federal Regulations 1943, Cum. Supp., p. 5224, as amended by 1946 Supp., p. 2952.

granted, after which the court issued a permanent injunction with appellants' consent. Appellants then devised a label on which it was stated that the products were intended for use in the treatment of four skin diseases, namely psoriasis, eczema, athlete's foot, and leg ulcers. Specific directions as to the method of use for these affections were incorporated in the label. The newspaper advertising was thereupon changed in such manner as to highlight these four diseases; but the advertising contained, in addition, reports of benefits derived in the treatment of other skin diseases not mentioned on the label, no adequate directions for use being given. Among the other skin affections referred to are poison ivy or oak, and acne, these conditions being mentioned in excerpts from testimonials received from doctors and druggists, and from letters from satisfied customers.

"Thereupon the government filed a contempt information containing nine counts, predicated on allegations of nine interstate shipments. The charge in each count is that appellants disregarded the injunctive orders in that the advertising material disseminated by them prescribed, recommended and suggested the use of the oil in the treatment of certain diseases in addition to the four mentioned on the label, and that adequate directions for using the remedy for those diseases were not printed on the label. The information is based on 21 USCA Section 332 (b). A jury and special findings were waived and upon trial to the court appellants were adjudged guilty on eight counts.

"Numerous arguments for a reversal are advanced, but few of which are worthy of discussion. The first point urged is that the court lacked jurisdiction of the subject matter and of the parties. There was no lack of jurisdiction of either. Appellants themselves appeared voluntarily. The Act prohibits the introduction into interstate commerce of any misbranded drug. 21 USCA Section 331 (a). A drug is deemed misbranded if its labeling bears inadequate directions for use, 21 USCA Section 352 (f) (1); and as appears in footnote 3 above the authoritative regulations declare directions inadequate if there is an omission of directions for use in all conditions for which the drug is prescribed, recommended or suggested in advertising matter sponsored by the manufacturer or distributor. The court's statutory authority for the issuance of the injunctions and for the trial of violations thereof is ample and has already been indicated.

"A large part of appellants' brief is devoted to collateral attacks on the injunctions, but since they were not appealed from and no modification was sought they are immune from challenge for mere error. It is settled law that unless an injunction is void its propriety must be tested by appeal and not by disobedience. *Clarke v. Federal Trade Commission*, 9 Cir., 128 F. 2d 542, and authorities there cited. Cf. also *United States v. United Mine Workers*, 330 U. S. 258, 293.

"As already seen, the injunctions prohibited appellants from introducing their Colusa Oil into commerce without a label containing adequate directions for use in the treatment of all conditions for which the product is 'prescribed, recommended and suggested' in their advertising material, that is to say, the key words in the orders were employed conjunctively, not disjunctively as they might have been under the administrative regulations. Colgrove was quick to seize upon the discrepancy, and he steered his course so as to sail as closely into the wind as he thought he safely could. His primary claim both below and here is that while the advertising matter relating to diseases other than the four mentioned on the label may be taken as 'recommending and suggesting' the use of the oil, its use is not therein 'prescribed' for the other diseases, hence the literal terms of the injunction were observed. We are of a contrary opinion.

"The advertisements address themselves to 'Skin Sufferers.' Photographs of the skin before and after treatment for eczema and leg ulcers are shown, and these two diseases, together with the remaining two mentioned on the labels, are named in large type. Following that, in small type, are columns headed 'summary of clinical reports on 28 cases,' 'thousands of doctors are Colusa customers,' 'excerpts from reports by druggists,' and 'thousands of users write letters of praise.' These subheadings refer indiscriminately, not only to the four diseases mentioned in the label, but also to acne and poison ivy or oak, and in the letters from lay users to a number of other skin conditions as well. We

append in the footnote excerpts from the material emanating from professional sources.⁴

"Little comment need be made on this advertising; it speaks for itself. Plainly the sponsor intended to be understood as adopting as his own the quoted statements of the doctors and professional dispensers of the preparation. That these would be taken by the lay reader as unqualifiedly prescribing the use of Colusa oil in the treatment of acne and poison ivy or oak, admits of no fair doubt.⁵ The term 'prescribe' is given the following definition by Webster: 'Med. To direct, designate, or order the use of, as a remedy.'⁶ The word 'designate,' in turn, is defined as 'to mark out and make known; to point out; to indicate.' Neither logic nor fairness requires a narrower definition of the term when employed in flamboyant advertising like the present. The word 'prescribe' of course includes recommending and suggesting.

"Other points urged are unworthy of specific attention.

"Affirmed."

The individual defendant filed a petition for certiorari with the United States Supreme Court on November 17, 1949, and this petition was denied on January 9, 1950.

3062. Misbranding of Powdr X. U. S. v. Lafayette M. Gray (L. M. Gray and Powdr-X Co.). Plea of not guilty. Tried to the jury. Verdict of guilty on counts 1 and 3 and not guilty on count 2. Fine of \$1,000 and costs. Judgment reversed by court of appeals and new trial ordered. Petition for certiorari denied by Supreme Court. Plea of nolo contendere. Fine, \$1,000. (F. D. C. No. 21482. Sample Nos. 43748-H, 43981-H, 44462-H, 52670-H.)

INFORMATION FILED: July 31, 1947, District of Minnesota, against Lafayette M. Gray, trading as L. M. Gray and the Powdr-X Co., Minneapolis, Minn.

ALLEGED SHIPMENT: Between the approximate dates of December 4, 1945, and March 23, 1946, from the State of Minnesota into the States of California and Indiana.

LABEL, IN PART: "Powdr X * * * Contents Silicon Dioxide, Aluminum Oxide, Ferric Oxide, Calcium Oxide, Magnesium Oxide, Sodium Oxide."

⁴"SUMMARY OF CLINICAL REPORTS ON 28 CASES—

"A doctor who owns a hospital in Texas reported under oath that in a clinic of 20 cases of psoriasis, 16 cleared of all lesions completely in 30 days—4 were 70% clear and continued treatment; that out of 40 cases of eczema all but three were cleared of all lesions in 3 weeks to a month with prognosis of the three good for recovery; that out of 11 cases of athlete's foot all, save one who did not return for treatment, were completely cured—8 to 14 days for acute cases and 3 weeks for chronic cases; that out of three cases of leg ulcers complete healing resulted in all 3 of the cases in a month; and in 8 cases of poison ivy or oak, complete cures were effected in an average of 5 days.' His report states, 'not in a single case of this clinical group did I meet with toxic bad effects . . . Intolerance or flare-ups . . . Colusa may be used near the eyes without danger . . . it relieves itching quickly. A little of the oil covers large areas. It is non-irritating. Soothing to raw and denuded lesions and affected areas. Easily massaged into the skin.'

"Two other doctors make similar glowing clinic reports—one, a United States Government health physician reporting on 25 cases, and the other a Mexican Government health physician reporting on 43 cases.

"THOUSANDS OF DOCTORS ARE COLUSA CUSTOMERS

EXCERPTS FROM A FEW OF THEIR REPORTS—

"New York—Dr. C.—practiced 10 years. . . (Case b) 'Poison ivy on entire body. Intense itching and swelling, itching stopped almost immediately on application of Colusa prod. and had entirely cleared in 5 days.'

"Ohio—Dr. H.—practiced 44 years. . . (Case b) 'acne, 3 cases, all improving.'

"EXCERPTS FROM REPORTS BY DRUGGISTS—

"Nebraska druggist—99% pleased customers. Stubborn cases: . . . 'Worked wonderfully acne.'"

⁵In the stipulation of facts made on trial the appellants impliedly concede that the advertising prescribed the use of the oil for the four diseases mentioned on the label. Colgrove appears to make a like concession in his oral testimony. There is no valid ground for the attempts to distinguish between the language employed in references to these four diseases and that relating to others referred to by the doctors and druggists.

⁶ Webster's New International Dictionary, 1937 Ed. Unabridged.

NATURE OF CHARGE: Count 1. Misbranding, Section 502 (a), the statement "In fact it is an ointment that is splendid for almost any infection, abrasions, or ulcers," appearing in a letter addressed to the consignee of the article, was false and misleading since the article would not be efficacious in the cure, mitigation, and treatment of almost any infection, abrasions, and ulcers; Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, namely, pumice; and Section 502 (f) (1), the labeling of the article bore no directions for use.

Count 2. Misbranding, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, namely, pumice; and, Section 502 (f) (1), the labeling of the article bore no directions for use.

Count 3. Misbranding, Section 502 (a), the statements "We have a very good reason for expecting Powdr-X to correct ulcers of the stomach * * * Gas pains that usually accompany ulcers of the stomach should subside in a week or ten days," appearing in a letter addressed to the consignee, were false and misleading since the article would not be efficacious in the cure, mitigation, and treatment of ulcers of the stomach; and, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, namely, pumice.

Count 4. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the cure, mitigation, and treatment of pernicious anemia, athlete's foot, cancer, colitis—mucous and ulcerative, enlarged glands causing stoppage of fluid, gall bladder infection, general debility, Hodgkin's disease, hyperacidity, osteomyelitis, piles (bleeding), hemorrhoids, poison ivy, poison oak, rheumatism other than arthritis, sinus infection, trench feet, trench mouth, tuberculosis of the bone, tuberculosis (pulmonary), stomach ulcers, varicose veins, and any and all cases of infection, which were the conditions for which the article was prescribed, recommended, and suggested in its advertising, disseminated and sponsored by and on behalf of its manufacturer and packer; and, Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article, namely, pumice.

DISPOSITION: A motion dated October 29, 1947, to dismiss the information on the ground that more than one offense was charged in each count, was filed on behalf of the defendant. Another motion dated October 29, 1947, for a bill of particulars in respect to counts 2 and 4 of the information was filed also on behalf of the defendant, requesting that the dates of shipment be alleged definitely and with particularity; that the name of the "manufacturer" and the name of the "packer" referred to in count 4 be given; and that certain details with respect to the "advertising" referred to in count 4 be specified.

On January 24, 1948, the court entered an order which denied the motions but which provided that the information be amended by the addition, at the end of each count, of the words "It being the intent and purpose of the plaintiff to charge hereunder, only one interstate shipment and offense under the Food, Drug, and Cosmetic Act," and by the change of the phrase "sponsored by and on behalf of its manufacturer and packer," set forth in Section 502 (f) (1), under count 4, so that it would read "and sponsored by and on behalf of defendant as manufacturer and packer aforesaid."

Thereafter, count 4 of the information was dismissed on the ground that subsequent investigation revealed that the interstate shipment was made more than three years prior to the filing of the information, so that the statute of limitation operated as a bar. A plea of not guilty was entered on behalf of the defendant on March 8, 1948, and on March 9, 1948, the case came on for trial before the court and jury. The trial was concluded on March 27, 1948, with the return by the jury of the following verdicts: Count 1, guilty of misbranding by reason of a label which was false and misleading, not guilty of failure to designate *Powdr X* as pumice, and not guilty as to inadequate directions; count 2, guilty of failure to designate *Powdr X* as pumice and not guilty as to inadequate directions; and count 3, guilty of misbranding by reason of a label which was false and misleading, not guilty of failure to designate *Powdr X* as pumice, and not guilty as to inadequate directions.

Subsequently, a motion for a judgment of acquittal, or, in the alternative, for a new trial, was filed on behalf of the defendant. At the opening of the hearing on the motion, the defendant withdrew its motion for a new trial, and, consequently, the motion for judgment of acquittal was the only matter involved. On May 11, 1948, the following decision in denial of the motion for judgment of acquittal was handed down:

NORDBYE, *District Judge*: "The above cause came before the Court on defendant's motion for judgment of acquittal, or, in the alternative, for a new trial. However, at the opening of the hearing on the motion, defendant withdrew its motion for a new trial, and therefore the motion for judgment of acquittal is the only matter which was presented.

"Defendant's motion for judgment is based on two grounds: (1) That the jury found defendant guilty only of offenses in support of which there was no evidence and with which he was not charged; and (2) there was no evidence to support a finding that the labeling was false and misleading because there was no evidence to support the finding that *Powdr-X* was not efficacious.

"The first ground is directed to the contention that, according to the form of the verdict submitted to, and returned by, the jury, the defendant was found guilty of offenses with which he was not charged in the information and in support of which there was no evidence at the trial. Defendant points out that, in Count I of the information, he was charged with misbranding within the meaning of 21 U. S. C. A. § 352 (a), in that the statement in the letter addressed to the consignee and accompanying the drug, 'In fact it is an ointment that is splendid for almost any infection, abrasions, or ulcers' was false and misleading in this, that said statement represented and suggested that said drug would be efficacious in the cure, mitigation and treatment of almost any infection, abrasions, or ulcers, whereas, in fact and in truth, said drug would not be efficacious in the cure, mitigation and treatment of almost any infection, abrasions, or ulcers; and that, in Count III of the information, defendant was charged with misbranding within the meaning of 21 U. S. C. A. § 352 (a) in that, accompanying said drug which was caused to be introduced into interstate commerce, there was a letter addressed to the consignee in which certain statements appeared, and the information sets forth that the statements 'We have a very good reason for expecting *Powdr-X* to correct ulcers of the stomach * * *. Gas pains that usually accompany ulcers of the stomach should subside in a week or ten days' were false and misleading in this, that said statements represented and suggested that said drug would be efficacious in the cure, mitigation and treatment of ulcers of the stomach.

"The defendant then points out that the form of the verdicts as submitted to the jury and as returned by the jury as to Counts I and III, finding the defendant guilty of misbranding, reads as follows:

We, the jury in the above-entitled action, find the defendant, as charged in the * * * information, guilty of misbranding by introducing into interstate commerce a drug, to wit, *Powdr-X*, with a label which was false and misleading: * * *

"Defendant's position is that he was not charged with introducing into interstate commerce a drug with a *label* which was false and misleading, but rather

that the *labeling* within the meaning of the Act was false and misleading. But a consideration of the entire situation would indicate that the motion for judgment on this ground seems to be extremely hypocritical and captious and must be rejected. Section 352, 21 U. S. C. A., reads:

A drug or device shall be deemed to be misbranded—

False or misleading label

(a) If its labeling is false or misleading in any particular.

Section 321 (m), Title 21 U. S. C. A., reads:

The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

"The Court in its charge went into considerable detail in setting forth the respective counts in the information, and specifically directed the jury's attention to the letter which was said to be sent to the consignee referred to in Count I and the contention of the Government that this letter was a labeling of the drug within the meaning of the law. The same detailed statement was made with reference to the letter sent to the consignee named in Count III, and which letter the Government contended was a labeling of the drug within the meaning of the law. As to both the letters in the Feltenberger and Evans counts, the Court stated:

I charge you that if they did accompany the shipments, in light of the instructions I have given you, then such letters constituted labeling within the meaning of the law, even though the letters were not physically attached to the cartons as labels. Consequently, if you find that Powdr-X was a drug within the meaning of the law, and if you further find that there was a labeling of the drug by the defendant within the instructions and definitions that I have given to you, then you will determine whether or not the labeling was false and misleading.

"In drawing the verdicts, the Court used the term 'with a label which was false and misleading' instead of 'with a labeling which was false and misleading.' But, obviously, in light of the Court's instructions, there was no possibility that the jury did not understand that when the Court used the term 'label,' it was with reference to the letter which accompanied the shipment and which would constitute a labeling under the Act if it accompanied the shipment, as explained in the Court's instructions. Strictly speaking, the term 'labeling' would have been more appropriate than the term 'label,' but, in that connection, reference may be made to the Act itself, which appears to use the term 'label' and 'labeling' interchangeably; that is, in the quoted part of Section 352, it will be noted that following the statement, 'A drug or device shall be deemed to be misbranded' appears a heading entitled 'False or misleading label,' followed by '(a) If its labeling is false or misleading in any particular.' And, to all intent and purpose, under Section 321 (m) any written matter accompanying the drug does become a 'label' within the meaning of the law.

"Strangely enough, the only one who was in any way concerned with the form of the verdicts in this regard was the Assistant United States Attorney, who, after the Court had instructed the jury, called to the Court's attention the use of the term 'label' in the verdicts instead of the term 'labeling' as follows:

When I mentioned the matter of the label and the labeling at the conclusion of your charge I didn't have in mind the significance of it as it was brought to my attention by Mr. Goding; and we had the reporter read back what was said to the jury with respect to these forms of verdict and we got copies of the forms which were placed with the jury. It appears that on the one, for instance, the Feltenberger, it should have read; "To wit, Powdr-X, with labeling," instead of "with a label which was false and misleading."

The Assistant United States Attorney suggested that a corrected form of verdict be submitted to the jury and that the jury be called back for that purpose. Counsel for the defendant, however, strenuously objected to the calling back of the jury as suggested by the Assistant United States Attorney, stating, among other things,

No objection was made to those forms of verdict by the Government and no exception to those forms of verdict was taken by the Government before the jury retired. It would be highly improper and without precedent whatever to now interfere with the deliberations of the jury for the purpose of giving them any other forms of verdict.

And after a colloquy between counsel, the Court stated to the attorney for the Government:

The jury can't possibly be misled by the form of verdict in so far as the term "label" is concerned. Certainly I went into great detail, and at your suggestion, after the jury was charged, called their attention to the fact that the labeling was not only the labeling which appeared by way of letter which accompanied the shipment, but was that which was attached to the carton. * * * Of course, my only purpose in using it was to identify the count—the various misbranding counts that appear in the respective counts, so that they could intelligently follow the instructions and intelligently return a verdict.

And at the close of the charge to the jury, after the Assistant United States Attorney had made some reference to the use of the term 'label' instead of the term 'labeling,' the Court stated to the jury:

Counsel have discussed some matters that possibly I should call to your attention. I instructed you regarding the question as to whether or not these letters would constitute labeling within the meaning of the law. Of course, if they are labeling within the meaning of the law that does not mean that the label on the carton itself is not a labeling. It would simply mean that in addition to the label on the carton you would have the labeling that may appear in the letters. I don't believe there should be any confusion in your mind about that, but in the event there is I hasten to clarify it.

"Certainly, there can be no possible question but that the jury understood that, when the Court used the term 'label' in the forms of verdict submitted to them, it was referring to the letters which had been written by the defendant containing the statements regarding the efficacy of Powdr-X. Days were spent in Court in endeavoring to decide whether or not the representations or statements made in these letters constituted a labeling which was false and misleading. In the main, the verdicts were drawn with considerable care so that the jury would be able to pass upon each phase of misbranding as set forth in the first, second and third counts. Granted that the word 'labeling' rather than the word 'label' would have been the better term to have used in the forms of verdict submitted, but to suggest now that the forms of verdict, to which no objection was made by the defendant and which the defendant in fact approved by his objection to any change therein, constituted any prejudice to the defendant is a sheer afterthought and seems highly hypercritical. There was no contention that the label affixed to the carton itself contained any false and misleading statements. The only label or labeling which contained any false and misleading statements, according to the Government's evidence was that which was set forth in the letters to Feltenberger and Evans. Obviously, therefore, the jury could not have been misled by the wording used in the forms of verdict submitted. When they returned verdicts of guilty as to misbranding by reason of a false and misleading label, they concluded that the Feltenberger and Evans letters constituted a labeling within the meaning of the law and that defendant's representations therein as to the medicinal value of Powdr-X were untrue under the evidence. The Court is clear that the first point urged in support of the motion for judgment of acquittal is utterly devoid of merit.

"The second ground urged in support of the motion for acquittal is apparently predicated on the theory that the medical experts produced by the Government either directly or indirectly conceded that they were assuming that Powdr-X was a pumice when they expressed an opinion that the drug had no therapeutic value. The defendant contends, therefore, that the jury having found that Powdr-X was not a pumice, it must necessarily follow that the opinions of the Government experts fall. The record indicates that the hypothetical question submitted to the Government medical experts did not incorporate an assumption that Powdr-X was a pumice, but rather that it was a volcanic ash. The question as propounded to the Government experts was substantially as follows:

Q. Doctor, I will ask you to assume that Powdr-X has been established as a volcanic ash, that is, that it is a volcanic glassy material, very finely divided, that the further testimony introduced into court shows that 5 grams of Powdr-X neutralizes 2 cc of 1/10 normal hydrochloric acid; that Powdr-X is not soluble in water and only slightly soluble in acid, and that as to the antiseptic qualities of Powdr-X it is inert to germs and bacteria. Now, assuming these facts I will ask you from your knowledge and experience as a physician, have you any opinion as to whether or not such a product, that is, Powdr-X, can be used in the treatment, that is, in the cure, mitigation, and treatment of infections or abrasions or external ulcers?

True, on cross-examination, and perhaps on direct, some of the Government experts admitted that they assumed in giving their opinions that Powdr-X was a pumice or its equivalent, volcanic ash. But it must be evident that the opinions of the doctors as to the efficacy of Powdr-X were based on the physical

and chemical properties thereof and not on the common, the mineralogical, or the geological name which might properly be ascribed to the drug itself. Whether Powdr-X is correctly designated as a pumice, volcanic ash, volcanic tuff, or a kaolin does not necessarily have any bearing on its efficacy or its therapeutic value in the treatment of the ailments and diseases referred to in the hypothetical questions. Rather, it is the physical and chemical properties of the drug which are the factors which would control. There was a great deal of testimony offered as to whether Powdr-X should have been labeled as a pumice, as that term is found in the National Formulary, and as to whether pumice was the common name for the substance. But whatever conflict there may have been on that issue, the evidence overwhelmingly indicated that the substance known herein as Powdr-X was originally of volcanic origin. Some of the Government witnesses referred to it as pumice or a volcanic ash, while some of the defendant's witnesses contended that it was more properly designated as a volcanic tuff. But whatever it might be called, it had certain chemical and physical properties which were controlling as the basis for the opinion given by the medical experts. All of the testimony, therefore, presented a fact question for the jury as to whether or not the substance known as Powdr-X had the medicinal properties which the defendant represented it had in the letters that he wrote to Mrs. Feltenberger and Mr. Evans. The jury found by its verdicts that the statements contained in these letters were false and misleading and there was ample evidence to sustain that finding. Moreover, the mere fact that the jury concluded that the Government had not sustained the burden of proof in establishing beyond a reasonable doubt that Powdr-X was a pumice does not mean that they concluded that it was not a volcanic ash or volcanic tuff, or a substance substantially the same or very similar to pumice. They may well have concluded that it was originally a volcanic ash, or a pumice, but, due to the effects of water erosion and other phenomena of nature, it had acquired certain clay-like properties and therefore could not strictly be classified as a pumice. But, whatever may have prompted the jury to reach the conclusion that it did, there is no inconsistency between its findings on that charge of misbranding, that is, the question as to whether or not the Powdr-X was a pumice, and its finding with reference to the charge of misbranding as to the truth of the representations made regarding the curative properties of this drug. And, whether the jury's findings of not guilty as to the other charges of misbranding was the result of compromise, mistake, or honest conviction, is obviously not for this Court to determine. The jury was required to make a finding as to whether or not Powdr-X had the curative properties which would enable it to alleviate and heal abrasions, cuts and ulcers. Evidently, the jury found that Powdr-X was without any curative properties in the particulars represented by the defendant, and that therefore the labeling was false and misleading. Any doubt that the jury may have had as to whether Powdr-X was a pumice under the evidence does not in any way militate against the soundness of its verdict in determining that the product was devoid of any medicinal value.

"As to whether or not a verdict should be set aside on the grounds of inconsistency of the findings on the several counts, see *Dunn v. United States*, 284 U. S. 390. While that case referred to the alleged inconsistency as among the several counts, and here we have an alleged inconsistency between the findings of misbranding included in one count, it would seem that the views of the Supreme Court therein are persuasive in the instant situation. Moreover, here we have no repugnancy in the jury's findings on the several charges of misbranding.

"The motion for judgment of acquittal, therefore, must be and is in all things denied. An exception is allowed."

On June 1, 1948, the court imposed a fine of \$1,000, plus costs (the amount of costs to be determined later), against the defendant. The defendant filed an appeal with the United States Court of Appeals for the Eighth Circuit, on June 17, 1948. On July 16, 1948, on motion of the Government's attorney, the court, after hearing, entered an order taxing costs in the amount of \$1,000. The court originally had approved costs in the amount of \$1,633.90, but after hearing, during which the defendant contended that this amount should be reduced because the Government had not been successful in sustain-

ing all its charges, the court reduced the amount of costs to \$1,000. (However, when the case was ultimately disposed of, no costs were imposed.)

On April 18, 1949, after consideration of the briefs and arguments of counsel, the United States Court of Appeals for the Eighth Circuit handed down the following opinion:

WOODROUGH, *Circuit Judge*: "The appellant was convicted and sentenced to pay a fine of one thousand dollars and costs for introducing into interstate commerce a certain drug called Powdr-X contained in packages and misbranded, in violation of the Federal Food, Drug and Cosmetic Act, § 301 (a) et seq., 21 U. S. C. A. 331 (a) et seq. The information against him contained four counts but the jury found him not guilty on count 2, and count 4 was dismissed during the trial. The judgment from which he appeals was entered upon the jury verdicts on the remaining counts of the information numbered one and three. Each of these counts was predicated upon one of the two shipments of packages of the drug made by appellant at Minneapolis, Minnesota; one shipment on December 6, 1945, to Mrs. H. Feltenberger at Culver City, Calif. (first count), and the other on March 23, 1946, to Ira J. Evans at North El Monte, Calif. (third count). The charge was to the effect that in each of the shipments the drug was misbranded in violation of the Act; (1) that the label upon each of the immediate containers was as follows:

"POWDR

X

Net Weight 8 oz.

CONTENTS

Silicon Dioxide, Aluminum Oxide,
Ferric Oxide, Calcium Oxide,
Magnesium Oxide, Sodium Oxide.

L. M. Gray, National Distributor
3856 Chicago Avenue
Minneapolis, Minn.
Phone Colfax 8295."

(2) that the appellant accompanied each shipment with a letter intended to be used together with the drug and constituting a labeling thereof, which letter he mailed to the consignee on the same day he made the shipment. In one of the letters it was stated that the drug was 'splendid for almost any infection, abrasion or ulcers' (first count), and in the other that 'We have good reason for expecting Powdr-X to correct ulcers of the stomach * * * 'Gas pains that usually accompany ulcers of the stomach should subside in a week or ten days,' which statements were false and misleading and in truth said drug would not be efficacious as stated; (3) that the drug was not designated by a name recognized in an official compendium and its label failed to bear the common or usual name of the drug, to-wit, pumice; (4)¹ the labeling failed to bear adequate directions for use, to-wit, there were no directions for use.

"Before entering his plea appellant moved to dismiss the information on the ground that each of the counts was duplicitous in that each attempted to charge more than one offense denounced by the Act, because each count² charged against him conduct alleged to be in violation of 21 U. S. C. A. 352 (a)³ and conduct alleged to be in violation of 21 U. S. C. A. 352 (e)⁴ and conduct alleged to be in violation of 21 U. S. C. A. 352 (f).⁵

"It was argued for the motion and is reiterated here that these three kinds of conduct connected with the shipment of drugs in interstate commerce, to-wit, (1) accompanying the shipment with a letter containing false statements;

¹ Count three did not include this specification (4) contained in count one.

² Except as above noted.

³ Section 352. Misbranded drugs and devices. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

⁴ (e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; * * *

⁵ (f) Unless its labeling bears (1) adequate directions for use.

(2) failing to put the true name of the drug on its 'label,' and (3) failing to include directions for use in its 'labeling,' should be deemed separate offenses and pleaded in separate counts under 18 U. S. C. A. 557 and Rule 8 (a) of F. R. C. P. It is stressed that the Act makes clear and positive distinction between conduct in respect to what the Act defines as the 'label' on the package of the drug and in respect to what it defines as the 'labeling' of the drug. 21 U. S. C. A. § 321 (k) provides that 'the term "label" means a display of written, printed or graphic matter upon the immediate container of any article; * * *,' and 21 U. S. C. A. § 321 (m) says that 'The term "labeling" means all labels and other written, printed or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.' The Act makes 'labeling' the broadly inclusive term and 'label' is narrowly confined to what is put on the immediate container. It is contended that writing and mailing a letter containing false statements about the drug is conduct so different in kind from failing to put required matter in its label or failing to put required instructions for use in either the letter or the label that the inclusion of charges of the three sorts of misconduct in each count made each count duplicitous.

"The trial court after consideration of the motion and argument, concluded that the charge in each count was single and not duplicitous in that the offense charged in each count was the introducing and delivering for shipment in interstate commerce of a misbranded article, in violation of 21 U. S. C. A. § 331 (a), which prohibits the introduction or delivery for introduction into interstate commerce of 'any * * * drug that is * * * misbranded,' under penalties provided in § 333 (a). It deemed the several acts and omissions charged against appellant to be specifications of the ways in which that offense was committed by him. We find no error in that ruling.

"But the court recognized that the offense in each count might be established under the information by proof of either one or all of the ways in which misbranding was charged to have been accomplished and it suggested to the prosecutor to amend the information by adding to it at the foot of each count the following: 'It being the intent and purpose of the plaintiff to charge hereunder only one interstate shipment and offense under the Food, Drug and Cosmetic Act.'

"The amendment having been made the motion was treated as being directed against the amended information and was denied, a plea of not guilty as to each count was entered and the trial proceeded before the court and jury over a period of 16 days. It was not disputed that the appellant had made the two shipments of the drug, each including a number of packages of the Powdr-X produced by grinding up a certain mineral substance found in volcanic formation on a ranch property in Colorado, nor that the packages shipped bore the label described in the information, nor that appellant caused the two shipments to be accompanied by the described letters mailed by him to the respective consignees, but the testimony of lay and expert witnesses on the questions as to what Powdr-X really was and whether or not it was pumice as charged and whether or not it had therapeutic capacities as represented in the letters was very voluminous and contradictory in respect to the inferences to be drawn from it.

"At the conclusion of its instructions to the jury the court delivered to the jury forms of verdict with blank spaces which the jury was directed to fill in with the words 'guilty' or 'not guilty,' according to the findings arrived at. The forms had been prepared by the prosecution and appear not to have been exhibited to appellant's counsel, or discussed before their delivery to the jury. There was one form for each of the three counts submitted to the jury but each form required the jury to make and declare more than one determination of 'guilty' or 'not guilty' upon each of the three counts submitted to it. Responding to count one, the form filled in by the jury with the words 'guilty' and 'not guilty' and returned into court as the jury's verdict on that count reads as follows:

Verdict as to First Count of Information (Feltenger)

We, the jury in the above entitled action, find the defendant, as charged in the first count of the Information . . . guilty of misbranding by introducing into interstate commerce a drug, to-wit, Powdr-X, with a label which was false and misleading; not guilty of misbranding by introducing a drug, to-wit, Powdr-X, in interstate commerce which was not designated solely by a name registered in an official compendium and that its label failed to bear the common name of the drug, to-wit, pumice; not guilty

of misbranding by introducing into interstate commerce a drug, to-wit, Powdr-X, which failed to bear adequate directions for use. (Feltenberger)

Dated this 27th day of March, 1948.

Richard A. Fancher
Foreman *

"As shown on the face of this verdict the jury undertook to make special declarations by use of the words 'guilty' or 'not guilty' in respect to particulars of misbranding described by paraphrases of parts of the information in the verdict-forms but the only matter in respect to which the jury found the appellant guilty was 'of misbranding by introducing into interstate commerce a drug, to-wit, Powdr-X, with a label which was false and misleading.' Responding specially to other particulars of the charges paraphrased in the verdict-forms, the jury wrote in the words 'not guilty.'

"The record shows that after the instructed jury had been deliberating for some hours without coming to agreement the prosecuting attorney in the presence of appellant's counsel indicated to the trial judge in chambers that mistakes had been made in the wording of the forms of the verdicts delivered to the jury which they were directed to fill out. The prosecutor used the verdict-form applicable to the first count for illustration and pointed out to the court that the wording of the form related the declaration of 'guilty' or 'not guilty' which the jury might write in the first blank space in the form, to 'a label' that was false instead of to 'labeling that was false' but there was no formal request or motion to recall the jury and make the correction. There was extended discussion in chambers between counsel on both sides and the judge, but it resulted in no action taken concerning the verdict-forms. The court indicated it was satisfied with the verdict-forms. Later the jury returned into court requesting further instructions but the matter of the verdict-forms was not then referred to. On the coming in of the verdicts the court entered judgment: 'It is adjudged that defendant has been convicted upon verdicts of guilty of the offense of misbranding by introducing into interstate commerce a drug, to-wit: Powdr-X, with a label which was false and misleading as charged in counts 1 and 3 of the information * * *,' and sentence was imposed as stated.

"At the conclusion of all the evidence the appellant had moved for verdict of acquittal and promptly after the verdict had been returned against him he again moved for judgment of acquittal. The motions were denied and he contends here that the rulings were erroneous.

"(1) In the first place he contends that in this criminal prosecution there was no power or discretion in the court to require the jury to return verdicts which were in the nature of the special interrogatories and answers thereto which are permissible in civil actions but which have no place in criminal procedure. His position is that a count in a criminal information must state only one offense; that the only permissible plea to it is guilty or not guilty or nolo contendere, and that upon the plea of not guilty the only issue for the jury joined by the charge of the count and the plea is the general issue of 'guilty' or 'not guilty,' and that the jury must be required to respond to that issue by a general verdict. His counsel took timely exception to the action of the court in submitting verdict-forms to the jury requiring multiple responses to each count on the ground that the forms 'required or permitted the jury to make a finding of guilty or not guilty three times in respect to count one, twice in respect to count two and twice in respect to count three,' and 'there is no authority by statute, by Federal Rules of Criminal Procedure, or by precedent of decision to permit such verdicts to be submitted to the jury for the purpose of returning verdicts in any criminal case; and upon the further ground that it in effect gives the jury an opportunity to arrive at some sort of a compromise which they might not arrive at if they were given verdicts which required them to find only once as to each of the three counts whether the defendant is guilty or not guilty.'

"In the argument here appellant's counsel again asserts that after diligent search he has found 'no statute, Rule of Criminal Procedure or precedent of decision' sanctioning the delivery of such a form of verdict to the jury for the purpose of returning their verdict in a criminal case or the requirement that the jury respond three times 'guilty' or 'not guilty' to one count of a criminal information. The prosecutor cites none and we find none. We think, as stated

* The form of verdict on count 3 was the same omitting the last not guilty finding.

by the court in *Anderson v. United States*, 273 F. 677, that 'it is not the practice of the federal courts in criminal cases to call for special verdicts.' c. f. *United States v. Noble*, 155 F. 2d 315. And we are constrained to conclude that the delivery of these forms to the jury and the direction to fill them out with several declarations of guilty or not guilty as to each count present an innovation in American criminal practice. It would serve no purpose to review the discussions of the courts and law writers concerning the use of special interrogatory and answer verdicts in civil actions. There are many well known arguments for and against the practice but no one doubts that the question whether it should or should not be followed is a question of due process and is important and far reaching. The vesting of discretion in the trial court to apply the practice in civil actions ultimately achieved by Rule 49 of the new Rules of Civil Procedure however is no indication of authority to use it in criminal trials. In such trials the practice has been settled time out of mind to charge but one crime in one count, to accept but one general plea to it and to call upon the jury to make but one general response, guilty or not guilty. Such established procedure was obviously departed from here over appellant's objection and it may not be held that such a departure did not affect appellant's substantial right to be tried according to law. It is not the function of the courts subordinate to the Supreme Court to introduce innovations of criminal procedure. The action of the court requiring the special verdicts duly excepted to by appellant constituted error.

"(2) Appellant also contends here, as he did upon his motion for acquittal made after verdict in the trial court, that the verdicts which purport to find him 'guilty of misbranding by introducing into interstate commerce a drug, to-wit, Powdr-X with a label which was false and misleading' were fatally defective and insufficient to support a judgment of conviction or sentence against him because the information did not charge him with that offense and there was no substantial evidence that he committed it.

"The record, considered with the provisions of the Act, has convinced that this contention for appellant is sound and that the verdicts are fatally defective. It is clear that the Act makes it a punishable offense to introduce a drug into interstate commerce 'with a label which is false and misleading.' 21 U. S. C. A. § 331 (a) prohibits such introduction of a drug that is misbranded; 21 U. S. C. A. § 352 (a) says that a drug is misbranded if its 'labeling' is false or misleading in any particular, and 21 U. S. C. A. § 321 (m) says that 'the term "labeling" means "all labels"' as well as other things. But in this information the only specification against the label with which the Powdr-X drug was shipped was that the label failed to bear the common or usual name of the drug. Although the label was set out in full in the information, it was not stated that the label was false or misleading and there was no proof that it was. It is beyond argument that a man can not, under the Fifth and Sixth Amendments, be convicted and sentenced for an offense not charged and not proven against him, and that is the situation in which this appellant stands upon the record before us. As succinctly stated by the Supreme Court a hundred and fifty years ago, 'A verdict is bad if it varies from the issue in a substantial matter,' *Patterson v. United States*, 2 Wheaton 221.

"It is argued for the government in support of the judgment that we may regard the opening words of the verdicts, 'We, the jury find the defendant as charged in the first count of the information guilty of misbranding,' to be a general verdict of guilty on the first count and may treat the remaining parts of the verdicts as surplusage. That is to say we should treat as surplusage not only the jury's specific finding that defendant was guilty of the certain clearly stated offense denounced by the Act in respect to 'a label which was false,' but also the two instances in the same verdict in which the jury says it finds the defendant 'not guilty of misbranding.' But we must decline to indulge in such unreasonable straining at the record. It is evident from the record that the jury was not required to and did not intend to render a general verdict on any count of the information here. It was erroneously required to render verdicts in the nature of special verdicts in answer to particulars of the information, and regardless of abstractions about the merits and demerits of that practice in general it is obvious that in this case it was the attempt to apply a sort of special verdict practice that resulted in the void verdicts. None of the numerous criminal cases in which surplusage added to general verdicts of guilty has been deemed harmless can be held to be applicable to the situation

here presented. Cf. *Statler v. United States*, 157 U. S. 277; *Patterson v. United States*, 2 Wheaton 221; *Samlin v. United States*, 278 Fed. 170.

"Here the jury did not mistakenly add inconsequential matter to a general verdict or anything that can fairly be called surplusage. It complied with the direction given by the court to make special response to special matter stated in paraphrases submitted to them. In consequence its verdict 'varied from the issue' and was 'bad.'

"It is further contended for the government that the only fair inference to be drawn from a reading of the whole record of the evidence, the proceedings and the instructions, together with the verdict, is that the jury must have meant that the statements in appellant's letters about the therapeutic efficacy of his drug, which were its labeling as defined by the Act, were false. We recognize that a verdict even in a criminal case need not be avoided because of slight or inconsequential ambiguity contained in it where that is dispelled entirely and the import is rendered clear and certain by the context of the record of which it forms a part. But the voluminous record here does not present any basis other than mere speculation to conclude that the jury meant to say that the appellant was guilty of anything other than the offense of which they found him guilty. Although the record shows that a great amount of testimony was directed to the issue of false labeling in the letters and we find sufficient evidence to justify a finding if one had been made that there was such false labeling, the fact remains that there was a dispute on that issue of the kind that can only be settled by a jury under our system. That there were differences among the jurors is manifest from the fact that they came into court asking to have their 'memories refreshed' as to testimony and as to the instructions and were out altogether twenty-seven and a half hours. But if their concurrence finally arrived at was in respect to the labeling found in the letters there was no place in the special forms they were required to fill out to so indicate. They did not so indicate. The conclusion is inescapable that the error in the proceeding was not a mistake in wording or phrasing made by laymen on the jury whose true intent may be verified by reference to other parts of the record. The fatal error was committed in requiring the jury to fill out a special form whose paraphrases included no reference to letters mailed by appellant and which did not permit the jury to make any response to the issue whether false labeling by means of the letters had or had not been committed by the appellant. It can only be concluded that the judgment of conviction is not supported by the verdicts.

"It is also argued that the appellant should be deemed to have waived the defects in the forms of verdict because he did not point them out to the court at the time the court delivered them to the jury. But the record shows that the court's attention was called to the defects both before the forms went to the jury and afterwards before the verdicts were arrived at. The court stated, 'The jury can't possibly be misled by the form of verdict in so far as the term "label" is concerned.' 'I can't conceive that there is anything but a rather captious objection to the word "label" as I used it in the verdict.' As this court's study of the record has led to contrary conclusions and to holding that in consequence of the defects in the forms it has resulted that there was no verdict of guilty of false labeling within the charge of the information, the onus of the outcome may not be shifted to the appellant. He was put in jeopardy on the charges of the several counts of the information and the jury was discharged without having rendered verdicts of guilty responding to the charges and he is therefore entitled to have the judgment against him avoided.

"Reversed and remanded with direction to set aside the judgment and discharge the accused."

A petition for rehearing was filed on behalf of the Government, with the United States Court of Appeals for the Eighth Circuit, and on June 6, 1949, an order was entered by that court denying the petition. The order provided, however, that the opinion filed April 18, 1949, be corrected by striking therefrom the last paragraph reading "reversed and remanded with directions to set aside the judgment and discharge the accused" and that there be substituted in lieu thereof the following "reversed and remanded with directions to set aside the judgment and grant a new trial." The order also provided that the judg-

ment of the court of appeals entered in pursuance of the opinion filed April 18, 1949, be corrected accordingly.

Following the entry of the order of June 6, 1949, a petition for rehearing was filed on behalf of the defendant, and on July 14, 1949, such petition was denied. A petition for a writ of certiorari was then filed by the defendant with the United States Supreme Court, and was denied by that court on October 17, 1949.

A motion for dismissal of the information was filed in the United States District Court for the District of Minnesota on March 1, 1950, and on March 9, 1950, the following decision was handed down by that court:

NORDBYE, *District Judge*: "This cause comes before the Court on defendant's notice of motion to dismiss each of the four counts in the information on the grounds set forth in said notice.

"This motion to dismiss is bottomed upon the contention that if defendant is tried again on the offenses alleged in the several counts of the information, he would be put in jeopardy a second time for the same offenses in violation of his rights under the Fifth Amendment to the Constitution of the United States. In that Count IV has already been dismissed by this Court because the offense charged therein has been barred by the statute of limitations, it follows that that count is no longer included in the information. Moreover, as to Count II, regardless of the alleged irregularity or innovation in the form of the verdict returned by the jury, it is my opinion that the verdict was one of not guilty and should be so considered. Consequently, that count will not be before the Court on any new trial to be had herein. That leaves Counts I and III to be considered on defendant's motion for a dismissal. In view of the Court's determination that a new trial may be had as to certain specifications of misbranding alleged in these counts, the following observations may be made.

"The Court of Appeals in its mandate directed this Court to set aside the judgment entered herein and grant a new trial. Defendant's petition for rehearing to the Court of Appeals dated July 1, 1949, was denied, and it is apparent that the only purpose of the petition was to obtain a modification of the Appellate Court's decision so as to eliminate the portion thereof which directed this Court to grant a new trial. In conformance with the mandate, this Court on October 29, 1949, set aside the judgment and sentence entered herein and granted a new trial. I must assume, in view of the opinion of The Court of Appeals and its refusal to make the modification requested by defendant, that it determined that a new trial as to Counts I and III would not place defendant in jeopardy a second time in violation of his constitutional rights. The refusal of the Supreme Court to grant a writ of certiorari has also been called to my attention.

"Now, whether we designate the forms of verdict returned in this case as special or general verdicts, and there is approval by the United States Supreme Court of so-called special verdicts being submitted in criminal cases where several acts are pleaded in separate counts, *Cramer v. United States*, 325 U. S. 1, 36, *Haupt v. United States*, 330 U. S. 631, 641, we have a finding of the jury herein that the defendant, on the evidence submitted and under the instructions of the Court, was not guilty of certain acts of misbranding as charged in these two counts. Therefore, in determining the specifications of misbranding as alleged in these two counts which should now be submitted to a jury on a new trial, I have concluded that I should hold that the specifications of misbranding in Counts I and III, as to which the jury's finding herein was that of not guilty, should be eliminated, and they hereby are withdrawn from further consideration on the retrial. This holding is in accordance with the view of the Government's counsel, as expressed in their brief in the Supreme Court of the United States on the petition of the defendant for a writ of certiorari.

"It follows, therefore, that as to Counts I and III, the specifications of misbranding by false and misleading labeling, as alleged in each of said counts within the meaning of 21 U. S. C. § 352(a), will constitute the sole remaining charges of misbranding which will be tried on the new trial herein. Defendant was instrumental in obtaining a vacation of the verdicts returned on Counts I and III and the judgment entered thereon, and in view of the

elimination by withdrawal of the specifications of misbranding of which defendant was found not guilty in these two counts, I am of the opinion that the new trial as to the remaining specifications of misbranding therein will not be in violation of defendant's constitutional rights. Defendant's motion to dismiss, except to the extent and in the manner as indicated herein, will be, and is, denied.

"An exception is allowed."

On March 21, 1950, the defendant changed his original plea of not guilty to a plea of *nolo contendere* on counts 1 and 3 of the information, as limited by the court's decision of March 9, 1950. On March 22, 1950, the court imposed a fine of \$1,000 without costs.

3063. Misbranding of Benzedrine Sulfate Tablets and sulfathiazole tablets. U. S. v. Samuel Price (Sam Price's Drug Store). Plea of *nolo contendere*. Fine, \$500. (F. D. C. No. 28150. Sample Nos. 53329-K, 53896-K, 53906-K, 54125-K, 54130-K, 54321-K.)

INFORMATION FILED: April 5, 1950, Eastern District of Louisiana, against Samuel Price, trading as Sam Price's Drug Store, New Orleans, La.

INTERSTATE SHIPMENT: Between the approximate dates of October 16, 1947, and May 16, 1949, from the States of Pennsylvania and Michigan into the State of Louisiana.

ALLEGED VIOLATION: On or about June 13, July 13 and 20, and August 11 and 26, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be removed from the bottles in which they had been shipped, to be repacked into small bottles, and to be sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; Section 502 (e) (1), the repackaged *Benzedrine Sulfate Tablets* failed to bear a label containing the common or usual name of the drug; Section 502 (f) (1), the repackaged *Benzedrine Sulfate Tablets* bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfathiazole tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: April 26, 1950. A plea of *nolo contendere* having been entered, the court imposed a fine of \$500.

3064. Misbranding of nembutal capsules, Benadryl Capsules, thyroid tablets, Tuinal Capsules, and Benzedrine Sulfate Tablets. U. S. v. Alden M. Clifford (Nu-Way Stores). Plea of guilty. Fine, \$150. (F. D. C. No. 28117. Sample Nos. 46088-K to 46092-K, incl., 61201-K.)

INFORMATION FILED: January 28, 1950, Western District of Missouri, against Alden M. Clifford, a partner in the partnership of Nu-Way Stores, Joplin, Mo.

INTERSTATE SHIPMENT: The drugs were shipped in interstate commerce into the State of Missouri prior to the dates of the sales of such drugs by the defendant, as hereinafter described.

ALLEGED VIOLATION: On or about July 11 and 12, 1949, and while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repackaged and sold to various

persons without a prescription, which acts of the defendant resulted in the repacked drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged *nembutal capsules*, *Benadryl Capsules*, and *Tuinal Capsules* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *nembutal capsules* and *Tuinal Capsules* contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the labels of the repackaged *nembutal capsules* and *Tuinal Capsules* failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *Benadryl Capsules* bore no label containing the common or usual name of the drug, namely Benadryl Hydrochloride; and, Section 502 (f) (1), none of the repackaged drugs bore labeling containing directions for use.

DISPOSITION: February 10, 1950. A plea of guilty having been entered, the court imposed a fine of \$150.

3065. Misbranding of nembutal capsules. U. S. v. William J. Parker. Plea of guilty. Fine, \$300. (F. D. C. No. 28105. Sample Nos. 51331-K, 51332-K.)

INFORMATION FILED: December 30, 1949, Southern District of Indiana, against William J. Parker, a pharmacist in a drug store at Richmond, Ind.

INTERSTATE SHIPMENT: On or about February 11, 1949, from Cincinnati, Ohio.

PRODUCT: When received by the defendant, the label of the product bore the statement "Caution—To be dispensed only by or on the prescription of a physician or dentist." As a result, the product was not required to comply with Section 502 (f) (1), which requires that adequate directions for use appear in the labeling.

NATURE OF CHARGE: On or about February 28, 1948, while a number of the capsules were being held for sale after shipment in interstate commerce, the defendant caused the capsules to be sold and disposed of to a purchaser in the original bottle in which the capsules had been shipped in interstate commerce, without a prescription of a physician or dentist. The sale of the capsules by the defendant caused the exemption to expire and resulted in the misbranding of the tablets in violation of Section 502 (f) (1), since the bottle bore no labeling containing directions for use.

On or about March 3, 1949, the defendant caused a number of capsules to be removed from the bottle in which they had been shipped in interstate commerce, to be repacked into a box, and to be sold without a prescription. The acts of the defendant resulted in the capsules being misbranded in violation of Section 502 (b) (2), in that the box of capsules bore no label containing a statement of the quantity of the contents; Section 502 (d), the label of the repackaged capsules failed to bear the name, and quantity or proportion of the chemical derivative of barbituric acid present in the drug and in juxtaposition therewith the statement "Warning—May be habit forming"; and, Section 502 (f) (1), the box of capsules bore no labeling containing directions for use.

DISPOSITION: February 27, 1950. A plea of guilty having been entered, the court imposed a fine of \$300.

3066. Misbranding of cancer treatment. U. S. v. 1 Vial * * *. (F. D. C. No. 28525. Sample No. 14967-K.)

LIBEL FILED: January 13, 1950, Northern District of Indiana.

ALLEGED SHIPMENT: Transported on or about December 4, 1949, by Dr. Eric P. Nauman, from the Hett Cancer Treatment and Research Foundation, Windsor, Ontario, Canada.

PRODUCT: 1 4-dram unlabeled vial containing a drug purporting to be a *cancer treatment* at Fort Wayne, Ind.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), it failed to bear a label containing an accurate statement of the quantity of the contents; Sections 502 (e) (1) and (2), the label of the article failed to bear the common or usual name of the article, or the common or usual name of each active ingredient thereof; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the conditions for which the article was intended.

DISPOSITION: February 21, 1950. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3067. Adulteration of sulfadiazine tablets. U. S. v. 3 Drums * * *. (F. D. C. No. 28253. Sample No. 11579-K.)

LIBEL FILED: October 31, 1949, District of New Jersey.

ALLEGED SHIPMENT: On or about September 19, 1949, by the Biddle Sawyer Corp., from New York, N. Y.

PRODUCT: 3 drums containing 538,000 *sulfadiazine tablets* at Jersey City, N. J.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insect fragments, wood splinters, paint fragments, plant fibers, glass fragments, soot, and nondescript dirt particles.

DISPOSITION: March 6, 1950. The Biddle Sawyer Corp., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the product be released under bond for salvaging, under the supervision of the Federal Security Agency. It was provided in the decree that the product should be salvaged by crushing the tablets and putting the crushed material through a chemical process which would extract the therapeutically valuable ingredient, sulfadiazine, from the contamination charged in the libel. The extracted sulfadiazine then was to be purified, so that it would comply with all requirements for sulfadiazine set forth in the U. S. Pharmacopoeia.

3068. Adulteration of B & S Syrup. U. S. v. 552 Bottles * * *. (F. D. C. No. 28407. Sample No. 33142-K.)

LIBEL FILED: December 2, 1949, District of Hawaii.

ALLEGED SHIPMENT: On or about November 3, 1949, from San Francisco, Calif. The product was shipped by the Boericke & Runyon Co., Inc., of San Francisco, Calif.

PRODUCT: 552 1-ounce bottles of *B & S Syrup* at Hilo, T. H.

LABEL, IN PART: "B & S Syrup For Coughs Due to Colds" * * * The Eopa Company Distributors San Francisco, Calif."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a decomposed substance by reason of the presence of mold.

DISPOSITION: March 22, 1950. Boericke & Runyon Co., Inc., San Francisco, Calif., having admitted the allegations of the libel and consented to the destruction of the product, judgment of forfeiture was entered and the court ordered that the product be destroyed.

3069. Adulteration of psyllium husks. U. S. v. 266 Bags * * *. (F. D. C. No. 28485. Sample No. 10082-K.)

LABEL FILED: December 29, 1949, Southern District of New York.

ALLEGED SHIPMENT: On or about January 20, 1949, from Bombay, India.

PRODUCT: 266 96-pound bags of *psyllium husks* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects. The article was adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: January 30, 1950. Peek & Velsor, Inc., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for reprocessing, under the supervision of the Federal Security Agency. The reprocessing operations were completed on or about March 27, 1950, and resulted in the destruction of 1,786 pounds of the product.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3070. Adulteration of chorionic gonadotropin. U. S. v. Associated Ross-Good Laboratories, Inc., Samuel Goodman, and Benjamin Ross. Pleas of nolo contendere. Fine of \$1.00 against corporation; each individual sentenced to 2 years in jail, which sentence was suspended, and each placed on probation for 4 years. (F. D. C. No. 28101. Sample Nos. 11266-K, 11294-K, 11296-K, 11332-K.)

INFORMATION FILED: December 30, 1949, Eastern District of Pennsylvania, against Associated Ross-Good Laboratories, Inc., Philadelphia, Pa., and Samuel Goodman, president of the corporation, and Benjamin Ross, secretary-treasurer.

ALLEGED SHIPMENT: On or about August 25, October 28, and December 17 and 24, 1948, from the State of Pennsylvania into the State of New York.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess. The article purported and was represented to be suitable and appropriate for parenteral administration, whereas it was not suitable and appropriate for such purpose since it was contaminated with viable micro-organisms.

DISPOSITION: February 28, 1950. Pleas of nolo contendere having been entered, the court fined the corporation \$1.00 and sentenced each individual to 2 years in jail, which sentence was suspended as to each individual, and each was placed on probation for 4 years.

3071. Adulteration of Kal-Estrin. U. S. v. Medi-Synth Laboratories, Inc. Plea of guilty. Fine, \$750. (F. D. C. No. 28176. Sample No. 40578-K.)

INFORMATION FILED: December 12, 1949, Southern District of California, against Medi-Synth Laboratories, Inc., Los Angeles, Calif.

ALLEGED SHIPMENT: On or about November 12, 1948, from the State of California into the State of Oregon.

NATURE OF CHARGE: Adulteration, Section 501(c), the strength of the article differed from that which it purported and was represented to possess. Each cubic centimeter of the article was represented to contain 20,000 International Units of estrogenic activity, whereas each cubic centimeter of the article contained a smaller amount of estrogenic activity.

The information alleged also that certain other products, namely, *Vitamin B complex tablets*, *Eight Essential Vitamins Capsules*, *Calcium Ration Tablets*, and *V. M. S. Tablets* were adulterated under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: January 30, 1950. A plea of guilty having been entered, the court imposed a fine of \$750.

3072. Adulteration and misbranding of prophylactics. U. S. v. 11 Gross * * * (and 1 other seizure action). (F. D. C. Nos. 28425, 28612. Sample Nos. 52359-K, 52364-K.)

LIBELS FILED: December 6 and 29, 1949, Middle District of Tennessee.

ALLEGED SHIPMENT: On or about November 16 and December 7, 1949, by the Klingfast Sales Co., from Atlanta, Ga.

PRODUCT: 29 gross of *prophylactics* at Nashville, Tenn. Examination of samples from each shipment of the product showed that 7.4 percent in one shipment and 8.3 percent in the other shipment were defective in that they contained holes.

LABEL, IN PART: "Klintab Caps."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the statement "Air and Water Tested," borne on the label of a portion of the article, was false and misleading as applied to an article containing holes.

DISPOSITION: March 14 and 15, 1950. Default decrees of destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3073. Misbranding of Garlex (garlic extract). U. S. v. 63 Bottles, etc. (F. D. C. No. 28684. Sample No. 54414-K.)

LIBEL FILED: January 11, 1950, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about November 23, 1949, by Crazy Water Co., Inc., from Mineral Wells, Tex.

PRODUCT: 63 8-ounce bottles, 135 16-ounce bottles, and 66 32-ounce bottles of *Garlex* (garlic extract), at New Orleans, La.

*See also Nos. 3062, 3072.

LABEL, IN PART: "Roberts Garlex * * * Compounded From Fresh Garlic Bulbs, U. S. Pure Glycerine and Mineral Wells Mineral Water Added * * * For Internal Use One Ounce * * * Shortly Before Meals Children— $\frac{1}{3}$ to $\frac{1}{2}$ the adult dosage * * * Texas Liquid Garlic Company."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article was an adequate and effective treatment for gastrointestinal symptoms accompanying arteriosclerosis and hypertension by inhibiting intestinal putrefaction and the formation of toxic products, and that it was an effective treatment for acute, subacute, and chronic diarrhea, enterocolitis, dysentery, digestive insufficiency, gastrointestinal dyspepsia, anorexia, excessive intestinal fermentation, meteorism, flatulence, intestinal colic, and subjective symptoms in arteriosclerosis, due to gastrointestinal disturbances. The article was not an adequate and effective treatment for such conditions.

DISPOSITION: February 23, 1950. Crazy Water Co., Inc., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

3074. Misbranding of Slim-O. U. S. v. 40 Bottles, etc. (F. D. C. No. 28484. Sample No. 67626-K.)

LABEL FILED: December 27, 1949, District of Colorado.

ALLEGED SHIPMENT: On or about November 5 and 6, 1949, by Beauty Sales, from Hollywood, Calif.

PRODUCT: 40 6-ounce bottles of *Slim-O* at Denver, Colo., together with a number of leaflets entitled "Beauty Sales" and a number of newspaper mats entitled "Lose Excess Fat." Examination showed that the product consisted essentially of epsom salt, sodium carbonate, and citric acid.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and a picture of a slender female appearing on the label of the article and in the leaflet and newspaper mats were false and misleading. The statements and picture represented and suggested that the article was the easiest, safest way to a beautiful, glamorous trim line figure; that the article would help one to take off inches of excess fat in the right spots, leaving the skin firm; that it would help one to lose excess fat and maintain a beautiful figure at all times; that it was effective for use on all parts of the chin, neck, and body; that with the aid of the article one could take off excess fat in the exact spots desired; that the article would dissolve and remove the excess fat from the skin tissues; that it would leave the skin firm and wrinkle-free; that there would be no risk of sagging tissues and wrinkles with use of the article; and that the article was a reducing aid. The article was not effective for the purposes stated and implied.

DISPOSITION: February 15, 1950. Default decree of condemnation and destruction.

3075. Misbranding of rectal suppositories. U. S. v. 36 Boxes * * *. (F. D. C. No. 28567. Sample Nos. 55881-K, 55882-K.)

LABEL FILED: On or about December 22, 1949, Western District of Missouri.

ALLEGED SHIPMENT: On or about May 20 and September 24, 1949, by the S. E. Massengill Co., from Bristol, Tenn.-Va.

PRODUCT: 36 boxes of *rectal suppositories* at Kansas City, Mo. Examination of samples showed that the product would not melt at body temperature.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Rectal Suppositories Aminophylline and Phenobarbital Sodium" was false and misleading since it implied that the article was suitable for the administration of aminophylline and phenobarbital sodium by rectum, whereas it was not suitable for such purpose since it would not melt at body temperature; and the label statement "Suppositories readily fuse or melt when exposed to body temperature" was false and misleading since the article would not fuse or melt at such temperature.

DISPOSITION: January 26, 1950. Default decree of destruction.

3076. Misbranding of Bath-O-Steam devices. U. S. v. 2 Devices, etc. (F. D. C. No. 28534. Sample No. 63645-K.)

LABEL FILED: On or about January 20, 1950, Southern District of Florida.

ALLEGED SHIPMENT: On or about September 16, 1949, by the Bath-O-Steam Corp., from West Alexandria, Ohio.

PRODUCT: 2 *Bath-O-Steam devices* at Orlando, Fla., together with a number of accompanying leaflets entitled "The Luxury of Turkish Steam Baths."

The device consisted of a square metal frame with a cover made of a plastic material, which when set up served as a home bath cabinet. An electric heating unit was supplied, together with a pan for heating water for a steam bath. The user was directed to sit inside the cabinet with the head or upper part of the body protruding.

LABEL, IN PART: (Leaflet) "All Electric Steam Bath or Dry Heat Sweat Bath Right In Your Own Home."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the accompanying leaflets were false and misleading since they represented and suggested that the device was effective for the purposes stated and implied, whereas it was not effective for such purposes: "Sweat Away Excess Fat Sooth Aches and Pains of Rheumatism, Arthritis, Colds Due to Body Poisons Relieve Nervous Tension * * * sweat away ugly excess fat and the poisons which cause colds; to soothe rheumatic and arthritic pains; to relieve tense nerves; and countless other benefits."

DISPOSITION: March 31, 1950. Default decree of condemnation and destruction.

3077. Misbranding of Detoxacolon Therapy Apparatus. U. S. v. 1 Device * * *. (F. D. C. No. 28072. Sample No. 53852-K.)

LABEL FILED: On or about October 24, 1949, Northern District of Alabama.

ALLEGED SHIPMENT: On or about June 2, 1949, by the United X-Ray & Equipment Co., from St. Louis, Mo.

PRODUCT: 1 *Detoxacolon Therapy Apparatus* at Decatur, Ala., together with a leaflet entitled "Let's Live" and a newspaper mat entitled "Something New Has Been Added." Examination showed that the device was one for mixing oxygen and water for administration as a rectal enema.

LABEL, IN PART: "Detoxacolon Therapy Apparatus Model 6 905 Serial No. 2920889."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Detoxacolon" and certain statements in the newspaper mat and leaflet were false and misleading since the device was not effective for the purposes, and was

not effective in the treatment of the conditions, stated and implied. The statements represented and suggested that the device would detoxify the colon; that it would tend to normalize the function of the colon; that lassitude and ill-being would disappear with the use of the device and be replaced by vitality and energy; that the device would correct conditions which cause many people to go to an early death; and that it would be effective in the treatment of headaches, asthma, hay fever, high blood pressure, low blood pressure, sinus trouble, arthritis, rheumatism, heart involvement, gall bladder trouble, neuritis, colitis, diabetes, liver dysfunctions, bloating, stomach trouble, kidney trouble, female disorders, epilepsy, sagging of the colon, spasticity, kinks, sharp bends, Bright's disease, stomach ulcers, cancer, dysentery, various types of constipation, spastic colon, intestinal ulcers and inflammation, nausea, vomiting, and bloody stools.

DISPOSITION: February 20, 1950. The United X-Ray & Equipment Co., Los Angeles, Calif., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the device be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

3078. Misbranding of *Watkins Multi-Vitamin Supplement For Livestock and Poultry*, *Watkins Niacin-Yeast Mix*, *Watkins Poultry Inhalant*, *Watkins Poultry Drinking Water Sanitizer*, *Watkins Mange Oil*, *Watkins Stock Mineral Compound*, and *Watkins Hog Mineral Compound*. U. S. v. 15 Drums, etc. (F. D. C. No. 28451. Sample Nos. 64142-K, 64143-K, 64176-K to 64180-K, incl.)

LIBEL FILED: December 2, 1949, Northern District of Iowa.

ALLEGED SHIPMENT: By the J. R. Watkins Co., from Winona, Minn. The products were shipped between the approximate dates of July 20 and October 10, 1949, and quantities of printed matter were shipped on or about March 10 and July 20, 1949, and during the 1½ years prior to November 1949.

PRODUCT: 15 60-pound drums of *Watkins Multi-Vitamin Supplement For Livestock And Poultry*, 6 100-pound drums and 7 25-pound drums of *Watkins Niacin-Yeast Mix*, 8 8-ounce bottles of *Watkins Poultry Inhalant*, 9 1-pint bottles of *Watkins Poultry Drinking Water Sanitizer*, 4 5-gallon cans of *Watkins Mange Oil*, 16 100-pound bags of *Watkins Stock Mineral Compound*, and 30 100-pound bags of *Watkins Hog Mineral Compound* at Schaller, Iowa, together with various pieces of printed matter entitled "Watkins Egg Record Chart," "Farmers: You Are Caught In The Squeeze," "Supplement Your Pastures With Watkins Minerals And Vitamins," "how to market more pigs per sow," and a loose-leaf folder containing 31 pages of testimonials.

LABEL, IN PART: "Watkins Multi-Vitamin Supplement For Livestock And Poultry * * * Ingredients: Vitamin A from Shark Liver Oil and Beta Carotene (from extracted alfalfa); vitamin D₃ from Shark Liver Oil and D-activated Animal Sterols; Soybean Oil Meal, Wheat Mill Feed, Riboflavin, Niacin, Non-Fermentable Yeast Culture (grown on corn, rye, malt and malt sprouts); Calcium Pantothenate and Animal Liver Meals."

"Watkins Niacin-Yeast Mix Vitamin Content Milligrams Per Pound Niacin (Nicotinic Acid) . . . 3,495 Micrograms Per Pound Thiamine (B₁) . . . 672 Riboflavin (Vit. G, B₂) . . . 4,049 Pantothenic Acid . . . 2,324 Choline . . . 28,530."

"Watkins Poultry Inhalant Active Ingredients: Propylene Glycol, Isopropyl Alcohol, Menthol, Eucalyptol, Pine Oil, Oil of Cade, Wetting Agent."

"Watkins Poultry Drinking Water Sanitizer * * * Ingredients Active Ingredient: Di-isobutyl phenoxy ethoxy ethyl dimethyl benzyl ammonium chloride monohydrate . . . 9.50% Inert Ingredients: . . . 90.50%."

"Watkins * * * Mange Oil * * * Active Ingredients 100% Mineral Seal Oil, Petroleum Distillate, Perfume and Orthophenylphenol."

"Watkins Stock Mineral Compound Composition —% Magnesium Carbonate . . . 5.500 Feeding Lime (Cal. Carb., 98% Pure) . . . 32.910 Sodium Chloride (Salt) . . . 9.500 Special Steamed Bone Meal . . . 12.000 Defluorinated Phosphate (Purified) . . . 31.000 Charcoal . . . 1.000 Sodium Bicarbonate . . . 2.000 Ferric Oxide (Iron Oxide) . . . 2.000 Copper Sulfate050 Manganese Sulfate050 Cobalt Sulfate065 Zinc Sulfate050 Potassium Iodide (Stabilized)150 Dried Molasses Fermentation Solubles . . . 3.500 Irradiated Yeast (Source of Vitamin D)150 Oil of Anise075 Total . . . 100.000 Contains 1,000 U. S. P. Units of Vitamin D per ounce of mineral."

"Watkins Hog Mineral Compound Composition —% Feeding Lime (Cal. Carb., 98% Pure) . . . 38.000 Special Steamed Bone Meal . . . 10.000 Defluorinated Phosphate (Purified) . . . 37.000 Sodium Chloride (Salt) . . . 6.000 Sodium Bicarbonate . . . 2.000 Charcoal500 Ferric Oxide (Iron Oxide) . . . 2.000 Iron Sulfate (Copperas)500 Copper Sulfate050 Manganese Sulfate050 Potassium Iodide (Stabilized)150 Dried Molasses Fermentation Solubles . . . 3.475 Irradiated Yeast (Source of Vitamin D)100 Cobalt Sulfate050 Zinc Sulfate050 Oil of Anise075 Total . . . 100.000 Contains 700 U. S. P. Units of Vitamin D Per Ounce of Mineral."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading since the articles were not effective for the purposes represented. The statements represented and suggested:

That the *Watkins Multi-Vitamin Supplement For Livestock And Poultry* was effective to prevent scours and necrotic enteritis in swine; to build resistance to infections and thus make a healthier flock of chickens; to aid digestion and help build resistance to disease, particularly diseases common to baby pigs; to keep livestock in a healthy and vigorous condition; to eliminate breeding troubles; to cause cattle to be contented and healthy; and to prevent "a sickness" or mortality from "a sickness" in chickens;

That the *Watkins Niacin-Yeast Mix* was effective to correct off-feed conditions; to prevent and to treat scours, necrotic enteritis in swine, and erysipelas; to keep livestock in a healthy and vigorous condition; to eliminate breeding troubles; to aid digestion and help their resistance to disease, particularly diseases common to baby pigs; to decrease the number of deaths among hens; and to eliminate susceptibility to disease in chicks;

That the *Watkins Poultry Inhalant* was effective to aid breathing of poultry affected with colds and minor bronchial irritations; to prevent colds, minor bronchial irritations, and breathing difficulties in baby chicks; and to aid in the treatment of colds, roup, and minor bronchial irritations;

That the *Watkins Poultry Drinking Water Sanitizer* was effective to aid in combating pullorum, cholera, typhoid, blackhead, trichomoniasis, intestinal coccidiosis, and other protozoan diseases of poultry; to aid in preventing

coccidiosis in pigs; and to help prevent the spread of blackhead, trichomoniasis, intestinal coccidiosis and other protozoan diseases;

That the *Watkins Mange Oil* was effective to prevent and treat mange in hogs;

That the *Watkins Stock Mineral Compound* was effective to prevent off-feed conditions, lack of vigor in calves at birth, breeding troubles, general unthriftiness, and inefficient production; to keep cows in perfect condition; to cause cattle to be contented and healthy; and to aid digestion;

That the *Watkins Hog Mineral Compound* was effective to prevent off-feed conditions, lack of vigor in pigs at birth, breeding troubles, general unthriftiness, and inefficient production; to keep one pig out of every three from dying; to prevent and treat scours, necrotic enteritis, and swine erysipelas; to keep livestock in a healthy and vigorous condition; to eliminate breeding troubles; and to aid digestion and help build resistance to disease, particularly diseases common to baby pigs.

DISPOSITION: December 31, 1949. The J. R. Watkins Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond for relabeling, under the supervision of the Federal Security Agency. On May 8, 1950, an order was entered by the court directing the destruction of the labeling by which the products were misbranded, as alleged in the libel.

3079. Misbranding of Dr. Martin's Sulfa Du. U. S. v. 12 Bottles, etc. (F. D. C. No. 28507. Sample No. 58631-K.)

LIBEL FILED: January 16, 1950, District of Utah.

ALLEGED SHIPMENT: On or about October 25, 1949, by the California Poultry Supply Co., from Los Angeles, Calif.

PRODUCT: 12 1-gallon bottles and 25 1-quart bottles of *Dr. Martin's Sulfa Du* at Salt Lake City, Utah, together with a booklet entitled "The Sulfa Story," a circular entitled "Does Chick Mortality cast a shadow over your Poultry Profits?" and a leaflet entitled "Is Your Head Swimming Too?"

LABEL, IN PART: "Dr. Martin's Sulfa Du * * * Sulfathiazole in soluble acid form, 22.2 gr. per fl. oz."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading. These statements represented and suggested that the article was effective in preventing and treating the disease condition of poultry known as infectious coryza; that the article would establish and maintain therapeutically effective sulfonamide blood levels in poultry; that it would stimulate food and water consumption and aid normal digestion; and that it was superior to adequate doses of sulfonamides in other forms. The article was not effective for the purposes, and was not capable of fulfilling the promises of benefit, stated and implied.

DISPOSITION: February 24, 1950. Default decree of condemnation and destruction.

3080. Misbranding of Dr. Martin's Sulfadine. U. S. v. 39 Bottles, etc. (F. D. C. No. 28531. Sample No. 29848-K.)

LIBEL FILED: January 16, 1950, District of Utah.

ALLEGED SHIPMENT: On or about August 5 and September 14, 1949, by the California Poultry Supply Co., from Los Angeles, Calif.

PRODUCT: 39 1-quart bottles and 3 1-gallon jugs of *Dr. Martin's Sulfadine* at Salt Lake City, Utah. Analysis showed that the product consisted of an acid solution of sulfaguanidine.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article was effective in the prevention and treatment of cecal coccidiosis of poultry, whereas the article was not effective in the prevention and treatment of cecal coccidiosis in poultry when used as directed, namely, "Directions: Add two tablespoonfuls (one ounce) to each gallon of all drinking water. For severe cases continue treatment for five full days * * * Allow only medicated water during treatment."

DISPOSITION: February 24, 1950. Default decree of condemnation and destruction.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 3061 TO 3080

PRODUCTS

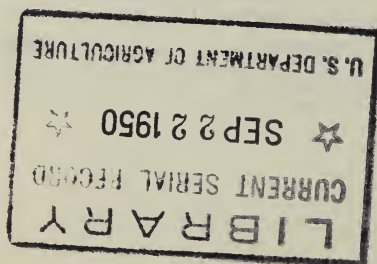
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Bath-O-Steam devices-----	3076	Powdr X-----	² 3062
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Cancer treatment-----	3066	Rectal suppositories-----	3075
Chorionic gonadotropin-----	3070	Reducing preparation-----	3074
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enteral drugs.		nary use)-----	3078
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Mange Oil, Watkins-----	3078	ment For Livestock and	
Martin's, Dr., Sulfa Du-----	3079	Poultry, Watkins Niacin-	
Sulfadine-----	3080	Yeast Mix, Watkins Poultry	
Multi-Vitamin Supplement For		Inhalant, Watkins Poultry	
Livestock And Poultry, Wat-		Drinking Water Sanitizer,	
kins-----	3078	Watkins Mange Oil, Watkins	
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Niacin-Yeast Mix, Watkins-----	3078	and Watkins Hog Mineral	
Parenteral drugs-----	3070	Compound-----	3078
Poultry Drinking Water Sani-			
tizer, Watkins-----	3078		

¹ (3061) Injunction contested. Contains opinion of the court.

² (3062) Prosecution contested. Contains opinions of the courts.

SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N. J. No.		N. J. No.
Associated Ross-Good Labora-		Klingfast Sales Co.:	
tories, Inc.:		prophylactics -----	3072
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Bath-O-Steam Corp.:		rectal suppositories-----	3075
Bath-O-Steam devices-----	3076	Medi-Snyth Laboratories, Inc.:	
Beauty Sales:		Kal-Estrin -----	3071
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Boericke & Runyon Co., Inc.:		A. M.	
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Dr. Martin's Sulfadine-----	3080	ette M.	
Clifford, A. M.:		Price, Samuel:	
nembutal capsules, Benadryl		Benzedrine Sulfate Tablets and	
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Colusa Remedy Co.:		Garlex (garlic extract)-----	3073
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Garlex (garlic extract)-----	3073	Watkins Multi-Vitamin Sup-	
Eopa Co.:		plement For Livestock and	
B & S Syrup-----	3068	Poultry, Watkins Niacin-	
Goodman, Samuel:		Yeast Mix, Watkins Poultry	
chorionic gonadotropin-----	3070	Inhalant, Watkins Poultry	
Gray, L. M. See Gray, Lafayette		Drinking Water Sanitizer,	
M.		Watkins Mange Oil, Watkins	
Gray, Lafayette M.:		Stock Mineral Compound,	
Powdr X-----	² 3062	and Watkins Hog Mineral	
Hett Cancer Treatment and Re-		Compound-----	3078
search Foundation:			
cancer treatment-----	3066		

¹ (3061) Injunction contested. Contains opinion of the court.² (3062) Prosecution contested. Contains opinions of the courts.

FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3081-3100

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., August 28, 1950.

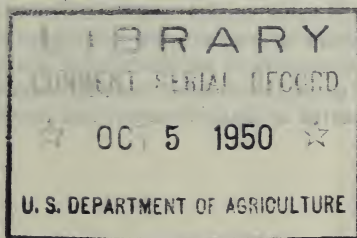
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897242-50



NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3081. *Paramycin Tablets*. U. S. v. 1 Bottle, etc. (F. D. C. No. 28754. Sample No. 3372-K.)

LABEL FILED: March 10, 1950, District of Columbia.

ALLEGED SHIPMENT: On or about February 24, 1950, by the Paramino Corp., from New York, N. Y.

PRODUCT: 1 1,000-tablet bottle and 3 100-tablet bottles of *Paramycin Tablets* at Washington, D. C.

LABEL, IN PART: "Enteric-Coated—0.5 gm. *Paramycin Tablets* (Para Amino-salicylic Acid) Caution: New drug, Limited by Federal Law to Investigational Use. Sole Distributors Paramino Corporation * * * New York, N. Y."

NATURE OF CHARGE: Section 505 (a), the article was a drug which should not have been introduced or delivered for introduction into interstate commerce since it was a new drug and an application filed pursuant to the law was not effective with respect to the drug.

DISPOSITION: April 12, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3082. *Misbranding of Tuinal Capsules and Benzedrine Sulfate Tablets*. U. S. v. The Eagle Drug Co., Leo F. Portman, and John Rundt. Pleas of guilty. Fine of \$300 against company, \$100 against defendant Portman, and \$200 against defendant Rundt, plus costs. (F. D. C. No. 28131. Sample Nos. 19309-K, 51661-K, 51837-K.)

INFORMATION FILED: March 10, 1950, Northern District of Ohio, against the Eagle Drug Co., a corporation, Canton, Ohio, and against John Rundt, president and treasurer, and Leo F. Portman, vice president and secretary, of the corporation.

INTERSTATE SHIPMENT: These drugs were shipped in interstate commerce into the State of Ohio. The *Tuinal Capsules* were shipped from the State of Pennsylvania and the *Benzedrine Sulfate Tablets* from the State of Indiana, prior to the dates of the sales referred to below.

ALLEGED VIOLATION: On or about January 26, May 23, and June 8, 1949, while the drugs were being held for sale after shipment in interstate commerce, the Eagle Drug Co. and John Rundt caused certain quantities of the *Tuinal Capsules* and *Benzedrine Sulfate Tablets*, and the Eagle Drug Co. and Leo F. Portman caused a quantity of the *Tuinal Capsules*, to be repackaged and sold to various persons without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "1½ grs.," borne on the label of a portion of the repackaged *Tuinal Capsules*, was false and misleading since the capsules contained more than 1½ grs. of the drug; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *Tuinal Capsules* contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the labels of the *Tuinal Capsules* involved

in one of the sales of that drug failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement, "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), none of the repackaged drugs bore labeling containing directions for use.

DISPOSITION: March 24, 1950. Pleas of guilty having been entered, the court fined the company \$300, defendant Portman \$100, and defendant Rundt \$200, plus costs.

3083. Misbranding of seconal sodium capsules and sodium amytal capsules. U. S. v. Ontario Pharmacy, Inc., and Joseph V. Gadzinski. Pleas of guilty. Fines of \$300 against corporation and \$900 against individual, plus costs. (F. D. C. No. 28118. Sample Nos. 15866-K to 15868-K, incl.)

INFORMATION FILED: January 17, 1950, Northern District of Illinois, against Ontario Pharmacy, Inc., Chicago, Ill., and Joseph V. Gadzinski, secretary-treasurer of the corporation.

INTERSTATE SHIPMENT: Prior to the date of the sales of the drugs by the defendant as hereinafter described, the drugs were manufactured in the State of Indiana and shipped in interstate commerce into the State of Illinois.

ALLEGED VIOLATION: On or about February 20, 22, and 23, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repackaged and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (b) (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the drugs contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged *seconal sodium capsules* bore no labeling containing directions for use.

DISPOSITION: April 10, 1950. A plea of guilty having been entered, the court fined the corporation \$300 and the individual \$900, plus costs.

3084. Misbranding of seconal sodium capsules, thyroid tablets, pentobarbital sodium capsules, and Metandren Linguets. U. S. v. Jack Golder (Pine Lawn Cut Rate Drugs). Plea of guilty. Fine, \$500. (F. D. C. No. 26738. Sample Nos. 45743-K, 45950-K, 45953-K to 45955-K, incl.)

INFORMATION FILED: October 12, 1949, Eastern District of Missouri, against Jack Golder, trading as Pine Lawn Cut Rate Drugs, at Pine Lawn, Mo.

INTERSTATE SHIPMENT: Between the approximate dates of October 2, 1947, and November 13, 1948, from Indianapolis, Ind., Chicago, Ill., and Summit, N. J., into the State of Missouri, of quantities of *seconal sodium capsules*, *thyroid tablets*, *pentobarbital sodium capsules*, and *Metandren Linguets*.

LABEL, WHEN SHIPPED: "Seconal Sodium 1½ grs.," "1 Grain Thyroid Tablets U. S. P.," "Pentobarbital Sodium Capsules Yellow 1½ grain U. S. P.," and

"Metandren Linquets * * * Each Linquet contains 10 mg. of Metandren (methyltestosterone U. S. P. XIII)."

ALLEGED VIOLATION: On or about January 20, 24, and 26, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused quantities of the drugs to be removed from the containers in which they had been shipped, to be repacked, and to be sold to various persons without a prescription, which acts by the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), they bore no label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), they were not designated solely by a name recognized in an official compendium, and their labels failed to bear the common or usual names of the drugs; and, Section 502 (f) (1), they bore no labeling containing directions for use.

Further misbranding, Section 502 (d), the repackaged *seconal sodium capsules* and the repackaged *pentobarbital sodium capsules* were drugs for use by man and contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, after investigation, found to be, and by regulations designated as, habit forming; and the labels of the repackaged drugs failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

DISPOSITION: March 17, 1950. A plea of guilty having been entered, the court imposed a fine of \$500.

3085. Misbranding of *seconal sodium capsules*, *pentobarbital sodium capsules*, *phenobarbital tablets*, *thyroid tablets*, and *sulfadiazine tablets*. U. S. v. Homer McCracken (McCracken Drug Store). Motions overruled to suppress evidence and to dismiss information. Plea of *nolo contendere*. Fine, \$500. (F. D. C. No. 25605. Sample Nos. 26963-K, 27744-K, 27770-K, 27771-K, 27819-K.)

INFORMATION FILED: March 10, 1949, Eastern District of Missouri, against Homer McCracken, trading as the McCracken Drug Store, St. Louis, Mo.

INTERSTATE SHIPMENT: Between September 26, 1947, and May 14, 1948, from the States of Indiana, New York, and Illinois, into the State of Missouri, of quantities of *seconal sodium capsules*, *pentobarbital sodium capsules*, *phenobarbital tablets*, *thyroid tablets*, and *sulfadiazine tablets*.

ALLEGED VIOLATION: Between May 26 and June 29, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets and capsules to be removed from the bottles in which they had been shipped, to be repacked into boxes, and to be sold to various persons without a prescription, which acts of the defendant resulted in the capsules and tablets being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (b) (2), the repackaged drugs bore no label containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *seconal sodium capsules*, *pentobarbital sodium capsules*, and *phenobarbital tablets* were drugs for use by man and contained chemical derivatives of barbituric acid, which

derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designed as, habit forming; and the labels of the tablets and capsules failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs failed to bear adequate directions for use since the directions for use "Directions one at bed time," on the labeling of the *seconal sodium capsules*, "Directions As directed," on the labeling of the *pentobarbital sodium capsules*, and "Two every 3½ to 4 hours," on the labeling of the *sulfadiazine tablets*, were not adequate directions for use, and since the labeling of the *phenobarbital tablets* and the *thyroid tablets* bore no directions for use; and, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: A motion to suppress evidence and a motion to dismiss the information were filed on behalf of the defendant; and on January 24, 1950, after consideration of the arguments and briefs of counsel, the court entered an order overruling the motions. On March 20, 1950, upon a plea of *nolo contendere* by the defendant, the court imposed a fine of \$1,000. On April 4, 1950, an order was entered amending the sentence to fix the fine at \$500 in lieu of the \$1,000 fine previously imposed.

3086. Misbranding of Parr's Golden-Ray Oil and Parr's Inhalers. U. S. v. 450 Bottles, etc. (F. D. C. No. 28739. Sample Nos. 52694-K, 52698-K.)

LABEL FILED: February 24, 1950, Western District of Kentucky.

ALLEGED SHIPMENT: On or about December 1, 1949, by the Cel-Ton-Se Medicine Co., from Cincinnati, Ohio.

PRODUCT: 450 bottles of *Parr's Golden-Ray Oil* and 143 *Parr's Inhalers* at Louisville, Ky., in possession of Thomas C. Williamson.

Examination showed that *Parr's Golden-Ray Oil* had essentially the composition stated on its label, and that the inhalers consisted of glass tubes, each containing a wad of cotton held in place by a perforated stopper.

LABEL, IN PART: "Parr's Golden-Ray Oil Relieve Symptoms of Colds by inhaling * * * For Coughs And Colds * * * For Stiff Joints And Sore Muscles * * * Active Ingredients Eucalyptus Oil, Menthol, Peppermint Oil, Thymol, Camphor" and "Parr's Inhaler Directions: * * * Parr's Golden-Ray Oil is non-toxic and harmless. Add more Oil to Inhaler twice weekly. The House Of Parr 333 Genessee St. Cincinnati 2, Ohio."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements in the labeling of the articles, namely, "For coughs and colds" and "For stiff joints and sore muscles," were false and misleading since the articles when used as directed were not an adequate and effective treatment for such conditions. The articles were misbranded in the above respects when introduced into, and while in, interstate commerce.

Further misbranding, Section 502 (a), certain statements in the accompanying labeling of the articles, namely, on a placard entitled "Do You Suffer from Headache" and on a circular entitled "Cold Sufferers," were false and misleading since such statements represented and suggested that the articles when used as directed were an adequate and effective treatment for headaches, colds,

coughs, asthma, catarrh, and hay fever, whereas the articles when used as directed were not an adequate and effective treatment for such conditions; and, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in the treatment of the conditions for which they were intended by their distributor, Thomas C. Williamson, namely, head colds, sinus trouble, chest colds, catarrh, arthritis, rheumatism, neuritis, lumbago, hay fever, asthma, high fever from a cold, tonsillitis, laryngitis, or in the prevention of laryngitis, pneumonia, or mastoid trouble. The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: March 27, 1950. Default decree of condemnation and destruction.

DRUG ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3087. Adulteration of Geo-Mineral. U. S. v. 121 Bottles * * *. (F. D. C. No. 28892. Sample No. 64186-K.)

LIBEL FILED: March 10, 1950, Northern District of Iowa.

ALLEGED SHIPMENT: On or about July 12, 1949, by the Vi-Jon Laboratories, from St. Louis, Mo.

PRODUCT: 121 3-ounce bottles of *Geo-Mineral* at Dubuque, Iowa.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy and decomposed substance by reason of the presence of mold. (The article was a water solution of ferric sulfate.)

DISPOSITION: May 2, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3088. Adulteration and misbranding of estrogenic substance. U. S. v. 34 Vials * * *. (F. D. C. No. 28540. Sample No. 52365-K.)

LIBEL FILED: January 31, 1950, Eastern District of Tennessee.

ALLEGED SHIPMENT: On or about September 10, 1948, by Estro Chemical Co., Inc., from New York, N. Y.

PRODUCT: 34 vials of *estrogenic substance* at Chattanooga, Tenn.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following label statements were false and misleading as applied to this article, which contained an amount of estrogenic substance derived from the urine of pregnant mares, of which 97% by potency was ketosteroids, calculated as estrone, only sufficient to give the article a potency, per cubic centimeter, of not more than 4,000 International Units: "Estrogenic Substance 20,000 I. U. per cc. * * * Each cc. of this material, when entirely suspended, contains a sterile suspension of Estrogenic Substance (predominantly Estrone) with small varying amounts of other Estrogens derived from the urine of pregnant mares. (Ketosteroids as Estrone, approximately 97% by potency.) Each 1 cc. is equivalent to 20,000 I. U. (assayed in terms of Estrone)."

DISPOSITION: April 21, 1950. Default decree. The court ordered that the product be delivered to the Food and Drug Administration.

3089. Adulteration and misbranding of suprarenin (epinephrine) tablets. U. S. v. 1,975 Tubes * * *. (F. D. C. No. 28487. Sample No. 48570-K.)

LIBEL FILED: December 19, 1949, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 12, 1949, from New Brunswick, N. J.
PRODUCT: 1,975 tubes each containing 20 *suprarenin* (epinephrine) *tablets* at Philadelphia, Pa.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, suprarenin bitartrate 0.00182 Gm. per tablet.

Misbranding, Section 502 (a), the label statement "Each tablet contains Suprarenin Bitartrate 0.00182 Gm. equivalent to Suprarenin 0.001 Gm. ($\frac{1}{65}$ grain)" was false and misleading as applied to an article which contained less than the stated amount of suprarenin bitartrate.

The article was adulterated and misbranded in the above respect while held for sale after shipment in interstate commerce.

DISPOSITION: February 2, 1950. Default decree of condemnation and destruction.

3090. Adulteration and misbranding of Sterilastic Dressing Bandage. U. S. v. 168 Packages * * *. (F. D. C. No. 28675. Sample No. 30240-K.)

LIBEL FILED: January 5, 1950, District of Massachusetts.

ALLEGED SHIPMENT: On or about November 25, 1949, from Los Angeles, Calif.
This was a return shipment.

PRODUCT: 168 packages of *Sterilastic Dressing Bandage* at Boston, Mass.

LABEL, IN PART: "Size 2" x 60" * * * Sterilastic Dressing Bandage
* * * Manufactured Only By Surgical Dressings, Inc., Boston, Mass."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Sterilastic First Aid Bandage * * * Surgical Dressing * * * The gauze supplied with Sterilastic may be used in an emergency" were false and misleading as applied to an article which was not sterile.

DISPOSITION: February 27, 1950. Default decree of condemnation and destruction.

3091. Adulteration and misbranding of prophylactics. U. S. v. 120 Gross * * *. (F. D. C. No. 28912. Sample No. 54766-K.)

LIBEL FILED: March 21, 1950, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about February 28, 1950, by the William Nesbit Co., from Pittsburgh, Pa.

PRODUCT: 120 gross of *prophylactics* at New Orleans, La. Examination of samples showed that 3.3 percent were defective in that they contained holes.

LABEL, IN PART: "Xcello's Prophylactics Mfd. By the Killian Mfg. Co. Akron, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statements "Prophylactics" and "Sold For Prevention of Disease Only" were false and misleading as applied to an article containing holes.

DISPOSITION: April 19, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3092. Misbranding of Adlerika. U. S. v. 13 $\frac{3}{4}$ Dozen Bottles * * *. (F. D. C. No. 29024. Sample No. 64194-K.)

LIBEL FILED: March 24, 1950, Northern District of Iowa.

ALLEGED SHIPMENT: On or about June 17 and November 10, 1949, by the Adlerika Co., from St. Paul, Minn.

PRODUCT: 13 $\frac{3}{4}$ dozen bottles of *Adlerika* at Dubuque, Iowa.

LABEL, IN PART: "Adlerika * * * combines the laxative properties of Magnesium Sulphate (Epsom Salt U. S. P.) Cascara and Licorice with * * * Fennel, Anise, Sassafras and Ginger * * * Carbonate of magnesia, Oil of Cinnamon, Methyl Salicylate and Glycerin."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in accompanying labeling consisting of a leaflet, circular, and display carton were false and misleading since they represented and suggested that the article would be effective to tone up the alimentary canal; that it would be effective in promoting a better sense of well being, toning up and conditioning the nutrition zone, promoting the assimilation of food, calming the stomach and intestines, and in treating headache, ulcers, inability to sleep, bad breath, rheumatism, backache, sore muscles, lumbago, arthritis, stomach ache, and obesity; and that it would be effective to promote relaxation. The article was not effective for such purposes.

DISPOSITION: April 25, 1950. Default decree of condemnation and destruction.

3093. Misbranding of V. M. Tablets. U. S. v. 6 Bottles, etc. (F. D. C. No. 28714. Sample No. 75432-K.)

LIBEL FILED: February 9, 1950, District of Colorado.

ALLEGED SHIPMENT: On or about January 2 and 16, 1950, from Chicago, Ill.

PRODUCT: 6 200-tablet bottles, 20 100-tablet bottles, and 46 25-tablet bottles of *V. M. Tablets* at Denver, Colo., in possession of Leed's Health House.

LABEL, IN PART: (Bottle) "V. M. * * * Also known as VegeMucene Okra Concentrated by dehydration."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement "Drugless Relief from Hyper-Acid conditions of Stomach Ulcers Colitis Gas With V. M. Tablets," appearing on a placard on display with the article in the window of Leed's Health House, was false and misleading in that the article was not an adequate and effective treatment for stomach ulcers, colitis, and gas. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 22, 1950. Default decree of condemnation and destruction.

3094. Misbranding of camphorated oil. U. S. v. 26 Dozen Bottles * * *. (F. D. C. No. 28857. Sample No. 48873-K.)

LIBEL FILED: February 15, 1950, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 3, 1949, from Newark, N. J.

*See also Nos. 3082, 3086, 3088-3091.

PRODUCT: 26 dozen ½-ounce bottles of *camphorated oil* at Scranton, Pa., in possession of Trager Mfg. Corp. The product was repackaged by the consignee after shipment.

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "For * * * Bruises * * * Pains and Swellings of the Breasts, Joints or Rheumatism" was false and misleading since the article was not effective in the treatment of such conditions; Section 502 (b) (1), the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2); the article failed to bear an accurate statement of the quantity of the contents. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 15, 1950. Default decree of condemnation and destruction.

3095. Misbranding of mineral oil. U. S. v. 92 Bottles, etc. (F. D. C. No. 28862. Sample No. 64633-K.)

LIBEL FILED: February 15, 1950, District of Minnesota.

ALLEGED SHIPMENT: On or about October 21, November 8, and December 13, 1949, from Whiting, Ind.

PRODUCT: 92 1-quart bottles and 37 1-gallon bottles of *mineral oil* at Minneapolis, Minn., in possession of L. S. Donaldson Co.

LABEL, IN PART: "White Mineral Oil U. S. P. Heavy."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "ideally adapted for expectant * * * mothers" was false and misleading since *mineral oil* may not be used without risk by pregnant women since it predisposes to hemorrhagic disease of the newborn. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: May 19, 1950. Default decree of destruction.

3096. Misbranding of vending machines and No. 5 Special Tablets. U. S. v. 12 Vending Machines * * * (and 1 other seizure action). (F. D. C. No. 28711. Sample No. 72462-K.)

LIBELS FILED: February 10, 1950, Southern District of Indiana.

ALLEGED SHIPMENT: The *vending machines* were shipped from Chicago, Ill., in October and November 1949, and the *No. 5 Special Tablets* were shipped from Columbus, Ohio, on or about October 5, 1949.

PRODUCT: 12 *vending machines* and 480 boxes of *No. 5 Special Tablets* at Indianapolis, Ind.

LABEL, IN PART: (Box) "No. 5 Special Tablets Contains: Thiamine Hydrochloride, Irradiated Yeast, Reduced Iron and Dibasis Calcium Phosphate with inert excipients. Distributed by Anstess & Fay, 2226 N. Meridian, Indianapolis, Ind. * * * Contents, Six Tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements which appeared in the labeling of each of the vending machines in which the tablets had been placed were false and misleading since the tablets contained in the vending machines, for vending therefrom, would not fulfill the promises of benefit stated and implied: "Get Vim Vigor Vitality With No. 5 Special No. 5 Special For Weak Glands of Men And Women Are You And Your Wife Happy If Not Try No. 5 Special." The tablets and the vending machines were misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: March 24, 1950. Default decrees of forfeiture. The court ordered that the tablets and nine of the vending machines be destroyed and that the remaining three vending machines be delivered to the Food and Drug Administration.

3097. Misbranding of Acme Electric Machine. U. S. v. 1 Device, etc. (F. D. C. No. 28742. Sample No. 61231-K.)

LIBEL FILED: March 8, 1950, Southern District of Illinois.

ALLEGED SHIPMENT: On or about February 9, 1948, by the T. O. Thomas Novelty Co., from Paducah, Ky.

PRODUCT: 1 *Acme Electric Machine* at Raymond, Ill., together with an accompanying circular entitled "The Acme Electric Machine."

The device consisted of a variable induction coil operated by a dry cell. Electrical energy was transmitted to the body through two handles, one of which could be turned to regulate the intensity of the current.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the label of the device and in the circular were false and misleading since the device was not capable of accomplishing the purposes or results stated and implied: (Device) "Electricity * * * Increases the Circulation: Purifies the Blood Improves the Health" and (circular) "Vibration is the Law of Life It is perhaps needless to state that the Medical profession has placed its sanction on the employment of Electric and Vibratory treatments for a multitude of ailments. It is also generally acknowledged that the majority of people will be benefited by such treatments."

DISPOSITION: April 5, 1950. Default decree of condemnation. The court ordered that the device be delivered to the Food and Drug Administration.

3098. Misbranding of Hollywood Silhouette Suits. U. S. v. 47 Suits * * *. (F. D. C. No. 28645. Sample No. 49667-K.)

LIBEL FILED: January 16, 1950, District of Colorado.

ALLEGED SHIPMENT: On or about October 11, 1949, by the Lucky Mfg. Co., from Los Angeles, Calif.

PRODUCT: 47 *Hollywood Silhouette Suits* at Denver, Colo. Examination showed that the suit was a coverall made of plastic. It was directed to be worn over a play suit, swim suit, or in the nude to produce sweating.

LABEL, IN PART: "Hollywood Silhouette Suit Portable Steam Bath."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statements "Look Better * * * Feel Younger * * * A Pleasant Easy Way to Lose Extra Pounds Quick" were false and misleading since the device was not effective to accomplish the results recommended since sweating will not bring about a reduction of weight and result in the user looking better and feeling younger.

DISPOSITION: April 4, 1950. The Lucky Mfg. Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUGS FOR VETERINARY USE

3099. Misbranding of Dr. Jespersen's Fowlton Concentrate, Dr. Jespersen's D. R. D. Concentrate, Dr. Jespersen's Flushem, and Dr. Jespersen's Gets-em Poultry Wormer. U. S. v. Dr. Aage P. Jespersen (Dr. Jesper-

sen's Laboratories). Plea of guilty. Fine of \$1,000, plus costs. (F. D. C. No. 28137. Sample Nos. 64120-K to 64123-K, incl.)

INDICTMENT RETURNED: March 29, 1950, Northern District of Iowa, against Dr. Aage P. Jespersen, trading as Dr. Jespersen's Laboratories, Spencer, Iowa.

ALLEGED SHIPMENT: Between the approximate dates of May 5 and 31, 1949, from the State of Iowa into the State of Minnesota.

LABEL, IN PART: "Dr. Jespersen's Fowlton Concentrate Manganese Iron Iodine Supplement for the Drinking Water for All Poultry," "Dr. Jespersen's D. R. D. Concentrate * * * Active Ingredients: Mercuric Chloride (16.4 grs. fl. oz.)," "Dr. Jespersen's Flushem Laxative For Poultry Contains—Active Ingredients, Magnesium Sulphate (Epsom Salts), Sodium Sulphate, Sodium Bicarbonate, 95%. Inert as a laxative—Sodium Thiosulphate and Gentian Violet 5%," "Dr. Jespersen's Gets-em Poultry Wormer * * * Contents: Arecoline Hydrobromide, Iron Chloride Solution, Solution Nicotine Sulphate, Copper Sulphate (22.5 grains per oz.) and Manganese Sulphate."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles, including the accompanying labeling consisting of an invoice headed "Dr. Jespersen's Laboratories Poultry Health Aids" and booklets entitled "Dr. Jespersen's Poultry Guide," were false and misleading since the articles would not be effective for the purposes, and would not fulfill the promises of benefit, stated and implied. The labeling of the articles represented and suggested that the articles would be effective to prevent losses of poultry, to insure better health of poultry, and to increase profits from poultry raising; that *Dr. Jespersen's Fowlton Concentrate* would be efficacious as a tonic and would be effective in the prevention and treatment of fowl cholera, fowl typhoid, blackhead of turkeys and chickens, and mycosis (mold poisoning); that *Dr. Jespersen's D. R. D. Concentrate* would be efficacious in the prevention and treatment of coccidiosis of chicks, white diarrhea, colds, and diphtheritic roup (pox); that *Dr. Jespersen's Flushem* would be efficacious for flushing poultry and in the prevention and treatment of mycosis; and that *Dr. Jespersen's Gets-em Poultry Wormer* would be effective to insure the growth and vitality of poultry, to increase egg production, to conserve feed, to promote resistance of birds to disease, and to act as a deterrent to the spread of disease in a flock; and that it would be efficacious in the prevention and treatment of worm infestation and paralysis.

DISPOSITION: April 12, 1950. A plea of guilty having been entered, the court imposed a fine of \$1,000, plus costs.

3100. Misbranding of Arnold Swerm Powder. U. S. v. 60 Bottles * * *. (F. D. C. No. 28721. Sample No. 63921-K.)

LIBEL FILED: February 14, 1950, Middle District of Georgia.

ALLEGED SHIPMENT: On or about October 14 and 25, 1949, by Arnold Laboratories, from New Castle, Ind.

PRODUCT: 60 1-pound bottles of Arnold Swerm Powder at Albany, Ga.

LABEL, IN PART: "Arnold Swerm Powder Each Ounce Contains: Calomel, a mercury derivative . . . 4.3 grains Arsenic Trioxide (1% of total) . . . 4.3 grains Areca Nut, Copper Sulfate, Sodium Chloride, Tobacco, Iron Sulfate, Magnesium Sulfate."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Partially effective for the removal of large round worms (Ascarids) from

swine" was false and misleading since the article was not effective for the purpose stated.

DISPOSITION: April 12, 1950. Default decree of condemnation and destruction.

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<i>Business Credit</i>	<i>Public Contracts</i>
<i>Communications</i>	<i>Public Lands</i>
<i>Customs</i>	<i>Securities</i>
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<i>Housing</i>	<i>Transportation</i>
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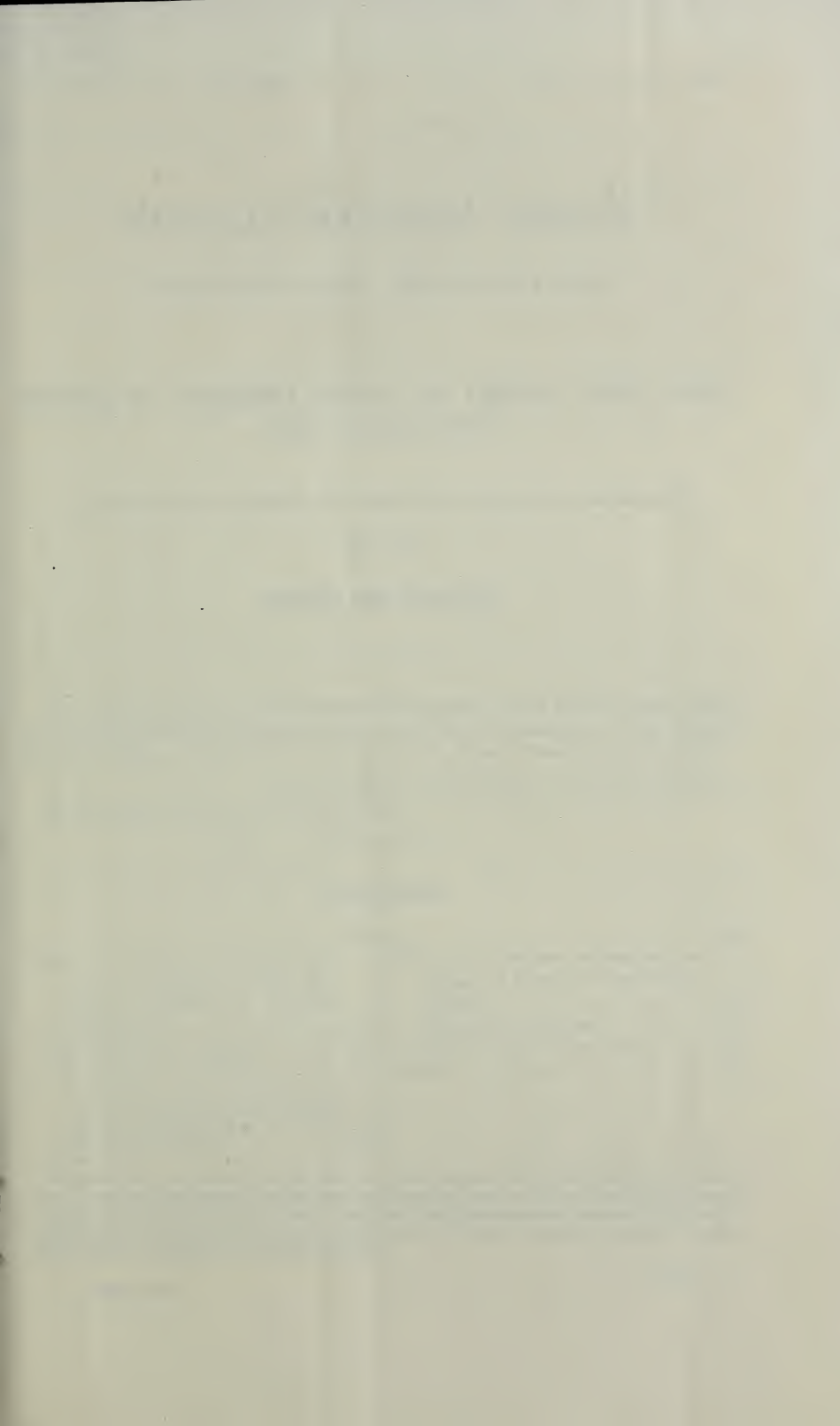
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FEDERAL SECURITY AGENCY**FOOD AND DRUG ADMINISTRATION****NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3101-3120

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., September 13, 1950.

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*For presence of a habit-forming narcotic without warning statement, see No. 3103; omission of, or unsatisfactory, ingredients statements, Nos. 3101, 3113, 3117; failure to comply with the packaging requirements of an official compendium, No. 3113; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3101, 3113; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3101, 3102, 3105.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3101. Misbranding of amphetamine hydrochloride tablets. U. S. v. David Avila (West Side Drug Store). Plea of guilty. Fine of \$250, plus costs. (F. D. C. No. 28132. Sample No. 49091-K.)

INFORMATION FILED: March 23, 1950, District of New Mexico, against David Avila, trading as the West Side Drug Store, Albuquerque, N. Mex.

INTERSTATE SHIPMENT: On or about August 9, 1949, from the State of Alabama into the State of New Mexico.

ALLEGED VIOLATION: On or about August 29, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendant caused a number of tablets of the drug to be removed from the bottle in which they had been shipped, to be repacked into a box, and to be sold without a prescription, which acts of the defendant resulted in the repackaged tablets being misbranded.

NATURE OF CHARGE: Misbranding, Section 502(b)(1), the repackaged tablets bore no label containing the name and place of business of the manufacturer, packer, or distributor; Section 502(b)(2), the repackaged tablets bore no label containing an accurate statement of the quantity of the contents; Section 502(e)(1), the repackaged tablets failed to bear a label containing the common or usual name of the drug, namely, "amphetamine hydrochloride"; Section 502(f)(1), the repackaged tablets bore no label containing adequate directions for use; and, Section 502(f)(2), the repackaged tablets bore no labeling containing warnings against use in those pathological conditions, and by children where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: April 18, 1950. A plea of guilty having been entered, the court imposed a fine of \$250, plus costs.

3102. Misbranding of Desoxyn Hydrochloride Tablets. U. S. v. James V. Thompson (Thompson's Drug Store). Plea of guilty. Fine of \$300 and costs. (F. D. C. No. 26743. Sample Nos. 37288-K, 37291-K.)

INFORMATION FILED: November 17, 1949, Western District of Washington, against James V. Thompson, trading as Thompson's Drug Store, at Lynden, Wash.

INTERSTATE SHIPMENT: Between the approximate dates of May 28 and August 5, 1948, from North Chicago, Ill.

PRODUCT: The product had been made for use exclusively by or on the prescription of a physician, and the label bore the statement "Caution: To be dispensed only by or on the prescription of a physician." As a result, the product was not required to comply with Section 502(f)(1), which requires that adequate directions for use appear in the labeling.

LABEL, WHEN SHIPPED: "Tablets Desoxyn Hydrochloride 2.5 mg."

ALLEGED VIOLATION: On or about September 10, 1948, while a number of tablets of the article were being held for sale after shipment in interstate commerce, the defendant caused them to be sold and disposed of to a purchaser in the original bottle in which the article had been shipped in interstate commerce, without a physician's prescription. The sale of the article by the defendant caused the exemption to expire and resulted in the misbranding of the article

*See also No. 3119 (veterinary preparations).

in violation of Section 502 (f) (1), since the bottle bore no labeling containing directions for use.

On or about September 30, 1948, the defendant caused a number of tablets to be removed from the bottle in which the tablets had been shipped in interstate commerce, to be repacked into a box, and to be sold without a prescription. The acts of the defendant resulted in the article being misbranded in violation of Section 502 (a), in that the statement "Desoxyn 2 gr.," displayed upon the box into which the tablets had been repacked, was false and misleading since each tablet of the article contained less than 2 grains of Desoxyn; Section 502 (b) (1), the box of tablets bore no label containing a statement of the quantity of the contents; Section 502 (f) (1), the box of tablets bore no labeling containing directions for use; and, Section 502 (f) (2), the box of tablets bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: April 4, 1950. A plea of quality having been entered, the court imposed a fine of \$300, plus costs.

3103. Misbranding of Sedco. U. S. v. 282 Bottles * * *. (F. D. C. No. 28710. Sample No. 47648-K.)

LIBEL FILED: February 7, 1950, Eastern District of Virginia.

ALLEGED SHIPMENT: On or about September 20, 1949, by the Hance Bros. & White Co., from Philadelphia, Pa.

PRODUCT: 282 1-pint bottles of *Sedco* at Norfolk, Va.

LABEL, IN PART: (Bottle) "One Pint Sedco Alcohol 5% Each Fluid Ounce Contains Sod. Pentobarbital $\frac{1}{2}$ gr. May be Habit Forming Phenobarbital $\frac{1}{2}$ gr. May be Habit Forming Ephedrine Sulphate 1 gr. tr Euphorbia 120 m Menthol $\frac{2}{25}$ gr. Syr. Squill Compound 21 m Syr. Wild Lettuce 120 m Tr Cocillana 40 m."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the label statement "Dose: As directed by the physician" failed to reveal the quantity of the dose and the frequency of administration.

Further misbranding, Section 502 (d), the article was a drug for use by man and contained derivatives of barbituric acid, namely, sodium pentobarbital and phenobarbital, which derivatives had been by the Federal Security Administrator, after investigation, found to be, and by regulations designated as, habit forming; and its label failed to bear the names, and quantities or proportions of all such substances and derivatives and the statement "Warning—May be habit forming" immediately following (without intervening written, printed, or graphic matter) the name by which the drug was titled in the part or panel of the label presented or displayed under customary conditions of purchase. The statement "Alcohol 5%" intervened between the name of the drug and the names of the habit-forming ingredients, and the prescribed statement was not in the form required by the law and regulations.

DISPOSITION: March 9, 1950. Coastal Pharmaceutical Co., Inc., Norfolk, Va., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for relabeling, under the supervision of the Federal Security Agency.

3104. Misbranding of Pancrelans Capsules. U. S. v. 11 Bottles * * *.
(F. D. C. No. 28709. Sample No. 69461-K.)

LABEL FILED: February 6, 1950, Western District of New York.

ALLEGED SHIPMENT: On or about January 13, 1950, by the Philadelphia Capsule Co., from Philadelphia, Pa.

PRODUCT: 11 100-capsule bottles of *Pancrelans capsules* at Buffalo, N. Y.

LABEL, IN PART: (Bottle) "Capsules 100 Pancrelans Approximates Special Pancreas $3\frac{1}{3}$ Grains Caution—To be used only by or on the prescription of a physician."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since it failed to bear any directions for use. The article was not entitled to exemption from the requirements of Section 502 (f) (1) and the regulations promulgated thereunder since adequate information for the use of the article was not readily available to physicians because it was inert and adequate information for its use as a drug, therefore, did not exist.

DISPOSITION: March 6, 1950. Default decree of condemnation and destruction.

3105. Misbranding of U-Ca-Lyp-To, U-Ca-Lyp-To Inhaler, Baker's Liquid for Corns and Callouses, Baker's Foot Balm, and Baker's Refined Lanolin Product. U. S. v. 393 Bottles, etc. (F. D. C. No. 28492. Sample Nos. 51970-K to 51974-K, incl.)

LABEL FILED: December 22, 1949, Southern District of Ohio.

ALLEGED SHIPMENT: Between the approximate dates of September 23 and November 12, 1949, from New York, N. Y.

PRODUCT: 393 bottles, ranging in size from 1-ounce to 32-ounces, and 1 1-gallon can, of *U-Ca-Lyp-To*; 468 *U-Ca-Lyp-To Inhalers*; 517 $\frac{1}{4}$ -ounce bottles of *Baker's Liquid for Corns and Callouses*; 126 4-ounce jars and 90 12-ounce jars of *Baker's Foot Balm*; and 37 4-ounce jars of *Baker's Refined Lanolin Product*, at Hamilton, Ohio.

Examination disclosed that the *U-Ca-Lyp-To* was an oil containing aromatics, including eucalyptol and camphor; and the *U-Ca-Lyp-To Inhalers* consisted of a glass tube containing a pledget of cotton, stoppered with a perforated cork; that the *Baker's Liquid for Corns and Callouses* contained salicylic acid, alcohol, ether, and pyroxylin; that the *Baker's Foot Balm* contained aromatics, including menthol, camphor, and eucalyptol; and that the *Baker's Refined Lanolin Product* was a perfumed ointment.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in the treatment of the conditions for which they were intended by Ervin G. Baker, their distributor. The articles were misbranded while held for sale after shipment in interstate commerce. The conditions for which the articles were intended were as follows: (*U-Ca-Lyp-To* and *U-Ca-Lyp-To Inhalers*) chronic cough, arthritis, neuritis, neuralgia, rheumatism, sciatica, lumbago, earache, and bleeding gums; (*Baker's Liquid for Corns and Callouses*) bunions, ingrown toenails, and warts; (*Baker's Foot Balm*) swollen ankles and insteps, ringworms, dermatitis, bunions, eczema, and impetigo; and (*Baker's Refined Lanolin Product*) the prevention and treatment of baldness and falling hair.

Further misbranding, Section 502 (b) (1), the label of the *Baker's Refined Lanolin Product* failed to contain the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: March 17, 1950. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3106. Adulteration of jalap root and cocillana bark. U. S. v. 12 Bags, etc. (F. D. C. No. 28229. Sample Nos. 57156-K, 57160-K.)

LIBEL FILED: October 26, 1949, Southern District of New York.

ALLEGED SHIPMENT: During August 1946 and May 1948, from Mexico and Bolivia.

PRODUCT: 12 bags, each containing 144 pounds, of *jalap root*, and 36 bales, each containing 90 pounds, of *cocillana bark* at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances by reason of the presence of (in the *jalap root*) insects and (in the *cocillana bark*) insect webbing and insect excreta, and the *cocillana bark* consisted in whole or in part of a decomposed substance by reason of the presence of mold. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 29, 1949. The Meer Corp., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond for segregation and destruction of the unfit portions, under the supervision of the Federal Security Agency. All of the *cocillana bark* and 202 pounds of the *jalap root* were subsequently destroyed.

3107. Adulteration of crude drugs. U. S. v. 36 Bags, etc. (F. D. C. No. 28061. Sample Nos. 57121-K, 57122-K, 57124-K to 57141-K, incl., 57143-K, 57144-K, 57148-K, 57150-K to 57153-K, incl.)

LIBEL FILED: November 2, 1949, Southern District of New York.

ALLEGED SHIPMENT: Between July 1945 and June 1949, from various States in the United States and from various foreign countries.

PRODUCT: 36 130-pound bags of *jalap root*; 159 92-pound bags of *flaseed husk*; 76 100-pound bags of *colombo root*; 56 165-pound bags of *scammony root*; 13 bales and 3 bags, containing a total of approximately 5,720 pounds, of *yellow dock root*; 24 bales, containing a total of approximately 9,015 pounds of *spikenard root*; 16 bags, each containing 120 pounds, and 7 200-pound bales, of *sarsaparilla root*; 8 50-pound bags of *blue flag root*; 26 110-pound bags of *angelica root*; 14 78-pound bags of *agaric root*; 141 313-pound bales of *licorice root*; 10 66-pound bags of *belladonna root*; 20 75-pound bags of *angelica seed*; and 6 105-pound bags of *dog grass root*, at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances by reason of the presence of insects. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 29, 1949. The Meer Corp., New York, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond for segregation and destruction of the unfit portions, under the supervision of the Federal Security Agency. The segregation operations resulted in the destruc-

tion of all the licorice root and certain portions of the other products, totaling approximately 10,745 pounds.

3108. Adulteration of crude drugs. U. S. v. 8 Bags, etc. (F. D. C. No. 27850.

Sample Nos. 11552-K to 11562-K, incl., 11565-K to 11578-K, incl.)

LABEL FILED: September 19, 1949, Eastern District of New York.

ALLEGED SHIPMENT: Between August 30, 1944, and April 8, 1949, from various States in the United States and from various foreign countries.

PRODUCT: 8 100-pound bags and 2 50-pound bags of *saw palmetto berries*, and 1 191-pound barrel of *granulated saw palmetto berries, dried*; 15 112-pound bags, 1 50-pound bag, and 18 117-pound bags of *hawthorne berries*; 17 40-pound bags of *stillingia root*; 1 162-pound bag of *Florentine orrisroot*; 5 150-pound bags of *stillingia root*; 27 120-pound bags of *Belgian burdock root*; 7 50-pound bags and 2 25-pound bags of *tonka bark*; 4 50-pound bags and 4 25-pound bags of *tonga vine*; 13 bales, containing 2,166 pounds, of *angelica root*; 24 110-pound bales of *Portuguese bryonia root*; 10 140-pound bales of *Spanish licorice root*; 50 62-pound bales of *corn silk*; 6 105-pound bags of *dandelion root*; 7 250-pound bales of *chiretta herb*; 3 162-pound bags of *Florentine orrisroot*; 3 191-pound barrels, 6 50-pound boxes, and 5 25-pound boxes of *powdered orrisroot*; 5 25-pound boxes and 1 46-pound box of *granulated orrisroot*; 2 91-pound bags of *psyllium husks*; 2 174-pound bags of *jambul seed*; 3 114-pound bags of *juniper berries*; 25 149-pound bags of *Verona orrisroot*; 15 bags, assorted sizes, of *black walnut hulls*; 21 bags, containing a total of 1,256 pounds, of *stillingia root*; 33 115-pound bags of cut *Belgian burdock root*; 1 205-pound bag of *dandelion root*; and 2 26-pound cartons of *granulated jambul seed*, at Brooklyn, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances by reason of the presence of insects in all of the articles, manure fragments in the hawthorne berries and black walnut hulls, and rodent pellets in the black walnut hulls; and the *stillingia root* also consisted in whole or in part of a decomposed substance by reason of the presence of mold. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: November 9, 1949. J. L. Hopkins & Co., Brooklyn, N. Y., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the products be released under bond for segregation and destruction of the unfit portions, under the supervision of the Federal Security Agency. The segregation operations resulted in the destruction of a total of 21,905 pounds of the drugs.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3109. Adulteration of distilled water. U. S. v. 4,900 Ampuls * * *. (F. D. C. No. 29032. Sample No. 48932-K.)

LABEL FILED: March 29, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about February 8, 1950, by Crescent Laboratories, Inc., from Trenton, N. J.

PRODUCT: 4,900 10-cc. ampuls of *distilled water* at Philadelphia, Pa.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Water for Injection," a drug the name of which

is recognized in the United States Pharmacopoeia, an official compendium, and its quality fell below the official standard since the article had a distinctive odor and taste. The Pharmacopoeia provides that water for injection be without odor and taste.

DISPOSITION: May 10, 1950. Default decree of condemnation and destruction.

3110. Adulteration and misbranding of chorionic gonadotropin. U. S. v. 18 Vials * * *. (F. D. C. No. 29016. Sample No. 57259-K.)

LIBEL FILED: March 16, 1950, Eastern District of New York.

ALLEGED SHIPMENT: On or about November 28, 1949, from Newark, N. J.

PRODUCT: 18 10-cc. vials of *chorionic gonadotropin* at Brooklyn, N. Y. Examination showed that the product contained approximately 5,600 International Units of *chorionic gonadotropin* per vial.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported to possess.

Misbranding, Section 502 (a), the label statement "10,000 I. U. * * * Chorionic Gonadotropin" was false and misleading since the article contained less than the stated amount of *chorionic gonadotropin*. The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 31, 1950. Default decree of condemnation and destruction.

3111. Adulteration and misbranding of Estrocrine Tablets. U. S. v. 33 Boxes * * *. (F. D. C. No. 28991. Sample No. 49677-K.)

LIBEL FILED: April 27, 1950, District of Colorado.

ALLEGED SHIPMENT: On or about January 20 and 25, 1950, by the Woodard Laboratories, from Los Angeles, Calif.

PRODUCT: 33 90-tablet boxes of *Estrocrine Tablets* at Denver, Colo. Examination showed that each tablet contained 0.014 milligram of alpha-estradiol.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 0.022 milligram alpha-estradiol per tablet.

Misbranding, Section 502 (a), the label statement "Each Tablet Contains: 0.022 Mg. Alpha Estradiol" was false and misleading.

DISPOSITION: June 6, 1950. Default decree of condemnation and destruction.

3112. Adulteration and misbranding of camphorated oil. U. S. v. 2 Gross Bottles * * *. (F. D. C. No. 29033. Sample No. 34742-K.)

LIBEL FILED: April 4, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about February 13, 1950, by Chemical Affiliates, from San Carlos, Calif.

PRODUCT: 2 gross bottles of *camphorated oil* at Longview, Wash. Examination of samples showed that the product contained not more than 15.1 percent of camphor.

LABEL, IN PART: "Camphorated Oil (Liniment Camphor, U. S. P.) * * * 2 Oz. Carlton Products Co. San Carlos, California."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as "Camphorated Oil," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard since the article contained less than 19 percent of camphor, the minimum permitted by the standard.

Misbranding, Section 502 (a), the label statement "Useful as an Application for Colds * * * and Bruises" was false and misleading since the article was not an adequate and effective treatment for colds and bruises.

DISPOSITION: May 5, 1950. Default decree of condemnation and destruction.

3113. Adulteration and misbranding of adhesive absorbent compresses. U. S. v. 3 Cartons * * *. (F. D. C. No. 29061. Sample No. 73683-K.)

LIBEL FILED: April 19, 1950, Southern District of New York.

ALLEGED SHIPMENT: On or about February 7, 1950, by the Wallich Laboratories, from Los Angeles, Calif.

PRODUCT: 3 cartons, each containing 100 unlabeled packages of 100 *adhesive absorbent compresses* each, at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents; Section 502 (e) (1), the article was not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the article. Further misbranding, Section 502 (g), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]," a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and it was not packaged as prescribed therein since such compendium provides that "Each Adhesive Absorbent Gauze is packaged individually in such manner that sterility is maintained until the individual package is opened. One or more individual packages are packed in a second protective container." (The compresses were not individually wrapped.)

DISPOSITION: June 21, 1950. Default decree of condemnation and destruction.

3114. Adulteration and misbranding of applicators with tongue depressor. U. S. v. 117 Cartons * * *. (F. D. C. No. 29055. Sample No. 40477-K.)

LIBEL FILED: April 10, 1950, District of Maryland.

ALLEGED SHIPMENT: On or about February 3, 1950, by Steri-Swabs, Inc., from New York, N. Y.

PRODUCT: 117 cartons, each containing 12 packages, of *applicators with tongue depressor* at Baltimore, Md. Examination showed that the product was not sterile but was contaminated with living micro-organisms.

LABEL, IN PART: (Package) "Sterile 10 Applicators With Tongue Depressor."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since the article was contaminated with living micro-organisms.

Misbranding, Section 502 (a), the label statements "Sterile When Packed" and "Sterile" were false and misleading as applied to a product that was not sterile.

DISPOSITION: May 17, 1950. Default decree of condemnation and destruction.

3115. Adulteration and misbranding of clinical fever thermometers. U. S. v. 2 Gross * * *. (F. D. C. No. 29035. Sample No. 60135-K.)

LIBEL FILED: April 7, 1950, Northern District of Illinois.

ALLEGED SHIPMENT: On or about December 16, 1949, by the Cardinal Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 2 gross of *clinical fever thermometers* at Chicago, Ill. Examination of 24 samples showed that 2 failed to meet the C. S. 1-32 specifications for retreating index and that 5 did not have the claimed accuracy of $\frac{2}{10}$ degrees at 98°, 102°, and 106° Fahrenheit.

LABEL, IN PART: "Clinical Fever Thermometers Description Illinois Stubby Oral."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to an article which failed to comply with the specifications stated: "Certification These thermometers have been manufactured according to the rules and regulations, and have been compared with the standard thermometers, verified by the United States Bureau of Standards" and "This Certifies that the enclosed thermometer bearing the above identification number has been tested on the above date at 98°, 102° and 106° F. and is correct within plus or minus $\frac{2}{10}$ F. at any of these test points. This test is governed by a Standard Thermometer which has been tested and approved by the Bureau of Standards, Washington, D. C. All our thermometers are manufactured in accord with their specifications. (C. S. 1-32 Department of Commerce.) The enclosed thermometer is guaranteed to be of absolute accuracy."

DISPOSITION: May 9, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3116. Misbranding of Y-N-I Tonic Tablets. U. S. v. 35,000 Tablets * * *. (F. D. C. No. 28747. Sample No. 64394-K.)

LIBEL FILED: March 7, 1950, District of Minnesota.

ALLEGED SHIPMENT: On or about September 17, 1949, by the Dietz Laboratories, from St. Louis, Mo.

PRODUCT: 35,000 Y-N-I Tonic Tablets at St. Paul, Minn.

LABEL, IN PART: "Y-N-I Tonic Tablets Each Tablet Contains: Po. Nux Vomica $\frac{1}{16}$ Gr., Peptonized Iron $\frac{3}{4}$ Gr., Cascarin Bitter $\frac{1}{4}$ Gr., Calcium Glycerophosphate $\frac{1}{8}$ Gr., Sodium Glycerophosphate $\frac{1}{8}$ Gr. Dehydrated Brewers Yeast 2 Grs."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the labels of the article "Tonic Tablets" and "to be taken by adults in need of a Tonic of this type for that tired run-down and pepless feeling" were false and misleading since the article was not a tonic and was not effective for the purposes stated.

DISPOSITION: May 16, 1950. Default decree of destruction.

*See also Nos. 3102, 3110-3112, 3114, 3115.

3117. Misbranding of Richard's Cough Syrup. U. S. v. 40 Dozen Bottles * * *. (F. D. C. No. 29102. Sample No. 72734-K.)

LABEL FILED: May 5, 1950, Southern District of Ohio.

ALLEGED SHIPMENT: On or about October 22, 1946, from Baltimore, Md.

PRODUCT: 40 dozen bottles of *Richard's Cough Syrup* at Athens, Ohio, in possession of Luster Fought & Co.

LABEL, IN PART: (Bottle) "Richard's Cough Syrup Alcohol 8% Chloroform 2 Minims per ounce Active Ingredients: Syrup White Pine and Tar, Menthol, Extract Henbane, Alcohol, Chloroform * * * 3 Fluid Ounces."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article were false and misleading since they represented and suggested that the article was an adequate and effective treatment for all affections of the throat, acute and chronic coughs, colds, hoarseness, sore throat, bronchitis, whooping cough, loss of voice, and chronic conditions, whereas the article was not an adequate and effective treatment for such conditions; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient and the quantity of chloroform and hyoscyamus (henbane) alkaloids contained therein. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: June 7, 1950. Default decree of destruction.

3118. Misbranding of Farador devices. U. S. v. 1 Device, etc. (and 1 other seizure action). (F. D. C. Nos. 28724, 28725. Sample Nos. 61615-K, 61617-K.)

LIBELS FILED: February 17, 1950, Southern District of Illinois.

ALLEGED SHIPMENT: On or about August 12, 1949, by the Forwarding Co., from Englewood, Ohio.

PRODUCT: 2 *Farador devices* at Quincy, Ill., together with a number of small cotton pads and one back plate for use with the device, and accompanying printed matter consisting of 2 direction books, 1 booklet entitled "Guard The Health of the Home," and 2 booklets entitled "We Submit Proof."

The device consisted of a metallic cylinder closed at both ends. To one end was attached, by means of wires, two metallic plates which were to be applied to various parts of the body while the cylinder was immersed in cold water.

LABEL, IN PART: "Sole Makers The Farador Co. 21313 Trade Mark Farador."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the direction books and in the booklets were false and misleading since the device was not adequate or effective for the prevention, treatment, and cure of the diseases, conditions, and symptoms stated and implied. The statements represented and suggested that the device was adequate and effective for the prevention, treatment, and cure of most of the diseases of the human body, including, but not limited to, appendicitis, blood poison, tuberculosis, syphilis, spinal meningitis, apoplexy, convulsions, sexual debility, epilepsy, gonorrhea, infantile paralysis, malaria, paralysis, and heart disease.

DISPOSITION: March 22, 1950. Default decrees of condemnation. The court ordered that the devices, the cotton pads, the back plate, and the books and booklets be delivered to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

3119. Misbranding of *Naxet*, A. D. N. Crumbles, *Anidene Jr.*, *Vi-Tox*, and *Men-O-Lac*. U. S. v. General Poultry Laboratories and George R. Sisson. Pleas of guilty. Fine of \$50 against defendants jointly. (F. D. C. No. 28095. Sample Nos. 44568-K to 44570-K, incl., 44580-K, 44582-K.)

INFORMATION FILED: December 1, 1949, District of South Dakota, against General Poultry Laboratories, a partnership, Sioux Falls, S. Dak., and George R. Sisson, a partner in the partnership.

ALLEGED SHIPMENT: On or about February 25 and April 1, 7, and 14, 1949, from the State of South Dakota into the States of Minnesota and Iowa.

PRODUCT: Analysis showed that the *Naxet* consisted essentially of hydrochloric acid, 32.9 grams per 100 milliliters of fish oil, 44.5 grams per 100 milliliters of dilute acetic acid, and other acids calculated as lactic acid in the amount of 2.1 grams per 100 milliliters; that the A. D. N. *Crumbles* consisted of a powder containing essentially plant material, including nux vomica alkaloids such as brucine and strychnine; tobacco alkaloid as nicotine in the amount of .67 percent, potassium iodide in the amount of .33 percent, together with chlorides, sulfates, calcium oxide, iron oxide, salts of sodium and potassium, and aromatics; that the *Anidene Jr.* was a red, aqueous, acid solution containing essentially 35.5 percent dilute acetic acid, 1.28 percent phenol, 1.61 percent mercuric chloride, together with borates, chlorides, sulfates, ammonium salts, zinc salts, sodium compounds, epsom salts, and glycerin; that the *Men-O-Lac* was a green powder containing essentially salts of calcium, sodium, copper, zinc, magnesium, in the form of phenolsulfonates, arsenite, borate, carbonate, sulfate, and coloring material; and that the *Vi-Tox* consisted of an amber, oily liquid containing essentially aromatics, such as oil of eucalyptus, creosote, possibly menthol and thyme, together with .024 percent iodine in a mineral oil base.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the *Vi-Tox* failed to bear adequate directions for use since there was no statement in the labeling of any condition, disease, and function of the bodies of poultry for which the article was to be used.

Further misbranding, Section 502 (a), the labeling of the other articles contained statements which were false and misleading since such articles when used as directed would not be efficacious for the purposes represented. The labeling represented and suggested that when used as directed the *Naxet* and the A. D. N. *Crumbles* would be efficacious as a tonic for poultry; that the *Anidene Jr.* would be efficacious in the cure, mitigation, and treatment of bowel disorders of poultry; and that the *Men-O-Lac* would be effective as a mild laxative for poultry.

DISPOSITION: March 22, 1950. Pleas of guilty having been entered, the court imposed a fine of \$50 against the defendants jointly.

3120. Misbranding of *Sal-Vet Poultry Tonic*. U. S. v. 37 Packages * * *. (F. D. C. No. 28977. Sample No. 46799-K.)

LIBEL FILED: April 19, 1950, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about January 13, 1950, by the *Sal-Vet Mfg. Co.*, from Cleveland, Ohio.

PRODUCT: 37 packages of *Sal-Vet Poultry Tonic* at Uniontown, Pa. Examination showed that the product contained no detectable amounts of vitamins A and D.

LABEL, IN PART: (Package) "Net Weight 3½ lbs. Sal Vet Brand Made With Cod Liver Oil Poultry Tonic."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "Made With Cod Liver Oil Poultry Tonic" was false and misleading since the article was not a tonic for poultry and did not supply vitamins A and D, which are important constituents of cod liver oil from the standpoint of poultry nutrition.

The article was alleged also to be misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: May 19, 1950. Default decree of condemnation and destruction.

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THE REGISTER

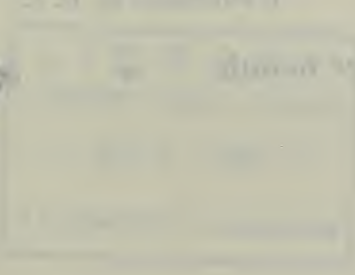
The Prince's Son of Ancestral Law

The Prince's Son of Ancestral Law is a story of a young man who is born into a family of nobles and is raised in a palace. He is a handsome young man with a kind heart and a strong sense of duty. He is the only son of the Prince and is the heir to the throne. He is a young man who is full of life and energy and who is full of a sense of purpose. He is a young man who is full of a sense of duty and who is full of a sense of responsibility. He is a young man who is full of a sense of honor and who is full of a sense of pride. He is a young man who is full of a sense of love and who is full of a sense of compassion. He is a young man who is full of a sense of justice and who is full of a sense of fairness. He is a young man who is full of a sense of truth and who is full of a sense of honesty. He is a young man who is full of a sense of loyalty and who is full of a sense of devotion. He is a young man who is full of a sense of courage and who is full of a sense of bravery. He is a young man who is full of a sense of strength and who is full of a sense of power. He is a young man who is full of a sense of wisdom and who is full of a sense of knowledge. He is a young man who is full of a sense of peace and who is full of a sense of harmony. He is a young man who is full of a sense of unity and who is full of a sense of brotherhood. He is a young man who is full of a sense of love and who is full of a sense of compassion. He is a young man who is full of a sense of justice and who is full of a sense of fairness. He is a young man who is full of a sense of truth and who is full of a sense of honesty. He is a young man who is full of a sense of loyalty and who is full of a sense of devotion. He is a young man who is full of a sense of courage and who is full of a sense of bravery. He is a young man who is full of a sense of strength and who is full of a sense of power. He is a young man who is full of a sense of wisdom and who is full of a sense of knowledge. He is a young man who is full of a sense of peace and who is full of a sense of harmony. He is a young man who is full of a sense of unity and who is full of a sense of brotherhood.

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9. The Prince's Son of Ancestral Law	9. The Prince's Son of Ancestral Law
10. The Prince's Son of Ancestral Law	10. The Prince's Son of Ancestral Law

The Prince's Son of Ancestral Law is a story of a young man who is born into a family of nobles and is raised in a palace. He is a handsome young man with a kind heart and a strong sense of duty. He is the only son of the Prince and is the heir to the throne. He is a young man who is full of life and energy and who is full of a sense of purpose. He is a young man who is full of a sense of duty and who is full of a sense of responsibility. He is a young man who is full of a sense of honor and who is full of a sense of pride. He is a young man who is full of a sense of love and who is full of a sense of compassion. He is a young man who is full of a sense of justice and who is full of a sense of fairness. He is a young man who is full of a sense of truth and who is full of a sense of honesty. He is a young man who is full of a sense of loyalty and who is full of a sense of devotion. He is a young man who is full of a sense of courage and who is full of a sense of bravery. He is a young man who is full of a sense of strength and who is full of a sense of power. He is a young man who is full of a sense of wisdom and who is full of a sense of knowledge. He is a young man who is full of a sense of peace and who is full of a sense of harmony. He is a young man who is full of a sense of unity and who is full of a sense of brotherhood.

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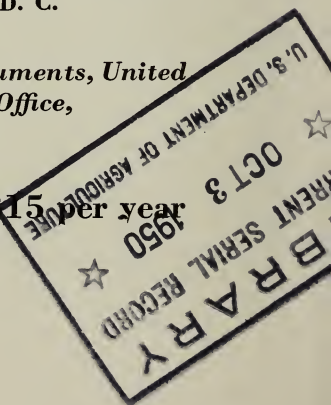
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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3121-3140

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

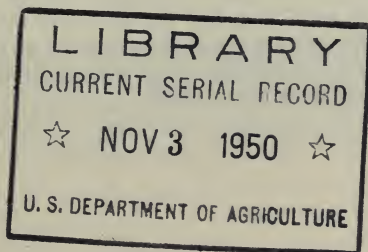
WASHINGTON, D. C., October 12, 1950.

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*For presence of a habit-forming narcotic without warning statement, see Nos. 3122-3126; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3122-3126; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3122, 3124-3126.

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DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

3121. Misbranding of penicillin sodium. U. S. v. 696 Cartons, etc. (F. D. C. No. 23191. Sample Nos. 64198-H, 64199-H.)

LABEL FILED: June 18, 1947, Southern District of New York.

ALLEGED SHIPMENT: On or about May 13, 1947, by Barich, Inc., from East Rutherford, N. J.

PRODUCT: 696 cartons, each containing 5 200,000-unit vials, and 9 cartons, each containing 5 500,000-unit vials, of *penicillin sodium* at New York, N. Y.

LABEL, IN PART: (Cartons) "Penicillin Sodium Proctor * * * Proctor Laboratories 475 Fifth Avenue New York 17, U. S. A."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the article was misleading since it failed to reveal the fact that Proctor Laboratories was not the manufacturer of the article, which fact was material in the light of the unmodified words "Proctor Laboratories" appearing in the labeling; and the label statements "Lot No. 77 * * * Oct-1-48" on the 200,000-unit vials and "Lot No. 90 * * * Oct 1 1948" on the 500,000-unit vials were misleading since they represented and suggested that the article had been certified under such identifying marks in accordance with regulations promulgated by the Federal Security Administrator, whereas the article had not been so certified.

Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (1), the article was represented as a drug composed wholly of *penicillin sodium*, a derivative of a kind of penicillin, and it was not from a batch with respect to which a certificate or release had been issued pursuant to the law.

DISPOSITION: June 1, 1950. The Proctor Laboratories having appeared as claimant and subsequently having withdrawn its claim, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3122. Misbranding of amytal tablets. U. S. v. Cosmopolitan Drug Co. and Charles M. Berman. Pleas of nolo contendere. Fine of \$100 and costs against company; fine of \$50 against individual. (F. D. C. No. 28103. Sample Nos. 42324-K, 43185-K, 43189-K.)

INFORMATION FILED: January 17, 1950, Northern District of Illinois, against the Cosmopolitan Drug Co., a partnership, Chicago, Ill., and Charles M. Berman, a pharmacist for the partnership.

INTERSTATE SHIPMENT: Between the approximate dates of October 20 and November 17, 1948, from the State of Indiana into the State of Illinois.

ALLEGED VIOLATION: On or about February 17, 18, and 23, 1949, while a number of *amytal tablets* were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the tablets to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged tablets being misbranded.

*See also No. 3121.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the tablets contained a chemical derivative of barbituric acid, which derivative has been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the repackaged tablets failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged tablets bore no labeling containing directions for use.

DISPOSITION: May 10, 1950. Pleas of *nolo contendere* having been entered, the court imposed a fine of \$100 and costs against the company and a fine of \$50 against the individual.

3123. Misbranding of Carbrital capsules. U. S. v. McDowell's Pharmacy and John Vance McDowell. Pleas of guilty. Individual fined \$500 on count 1 and assessed costs on counts 2 and 3; pharmacy also assessed costs, which were suspended. (F. D. C. No. 28128. Sample Nos. 19355-K, 52048-K, 52054-K.)

INFORMATION FILED: February 8, 1950, Northern District of Ohio, against the McDowell's Pharmacy, a partnership, Akron, Ohio, and John Vance McDowell, a partner in the partnership.

INTERSTATE SHIPMENT: Between the approximate dates of June 24 and August 8, 1947, from the State of Michigan into the State of Ohio.

ALLEGED VIOLATION: On or about June 10, 17, and 29, 1949, while a number of *Carbrital capsules* were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the capsules to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear a label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the *Carbrital capsules* contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged capsules bore no labeling containing directions for use.

DISPOSITION: June 7, 1950. Pleas of guilty having been entered, the court imposed a fine of \$500 on count 1 and assessed costs in the amount of \$21.10 on counts 2 and 3 against the individual defendant. The court also assessed costs in the amount of \$21.10 against the partnership, which costs were suspended.

3124. Misbranding of sodium pentobarbital capsules and seconal sodium capsules. U. S. v. Jay Leonard Bumpas (Bumpas Drug Store), and Bailey Ammons. Pleas of *nolo contendere*. Fine of \$250 against defendant Bumpas and \$100 against defendant Ammons. (F. D. C. No. 28140. Sample Nos. 56043-K to 56046-K., incl., 56049-K.)

INFORMATION FILED: March 22, 1950, Western District of Oklahoma, against Jay Leonard Bumpas, trading as the Bumpas Drug Store, Frederick, Okla., and against Bailey Ammons, a pharmacist employed at the drug store.

INTERSTATE SHIPMENT: On or about May 13, 1948, and January 28, 1949, from the States of New York and Indiana into the State of Oklahoma.

ALLEGED VIOLATION: While a number of *sodium pentobarbital capsules* and *seconal sodium capsules* were being held for sale after shipment in interstate commerce, the defendants caused, on or about February 17 and March 23, 1949, various quantities of the *sodium pentobarbital capsules* to be repacked and sold without a prescription; and, in addition, Jay Leonard Bumpas caused, on or about March 22 and 23, 1949, various other quantities of *sodium pentobarbital capsules* and a quantity of *seconal sodium capsules* to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules failed to bear labels containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear labels containing the name, and quantity or proportion of each such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use since the repackaged *sodium pentobarbital capsules* bore no labeling containing directions for use and since the directions "One at bedtime as needed for rest" on the labeling of the repackaged *seconal sodium capsules* were inadequate; and, Section 502 (b) (1), the repackaged *sodium pentobarbital capsules* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor.

DISPOSITION: May 9, 1950. Pleas of *nolo contendere* having been entered, the court imposed a fine of \$250 against defendant Bumpas and a fine of \$100 against defendant Ammons.

3125. Misbranding of seconal sodium capsules. U. S. v. Fair Price Drug Corp., Leo Mesirow, and Leo Levinson. Pleas of *nolo contendere*. Fine of \$300 against corporation; fine of \$100 against each individual defendant. (F. D. C. No. 28102. Sample Nos. 15876-K, 15877-K.)

INFORMATION FILED: January 18, 1950, Northern District of Illinois, against the Fair Price Drug Corp., Chicago, Ill., and against Leo Levinson and Leo Mesirow, president and secretary, respectively, of the corporation.

INTERSTATE SHIPMENT: Between the approximate dates of September 10, 1948, and February 16, 1949, from the State of Indiana into the State of Illinois.

ALLEGED VIOLATION: On or about April 1 and 5, 1949, while a number of *seconal sodium capsules* were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the capsules to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (b) (2), the repackaged capsules failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative has been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged capsules bore no labeling containing directions for use.

DISPOSITION: June 12, 1950. Pleas of *nolo contendere* having been entered, the court imposed a fine of \$300 against the corporation and a fine of \$100 against each individual.

3126. Misbranding of seconal sodium capsules. U. S. v. Mesirow-Madison Drugs, Inc., and Abe R. Segal. Pleas of *nolo contendere*. Fine of \$250 against each defendant. (F. D. C. No. 28100. Sample Nos. 15871-K to 15873-K, incl.)

INFORMATION FILED: January 17, 1950, Northern District of Illinois, against Mesirow-Madison Drugs, Inc., Chicago, Ill., and Abe R. Segal, president of the corporation.

INTERSTATE SHIPMENT: Between the approximate dates of January 19 and February 11, 1949, from the State of Indiana into the State of Illinois.

ALLEGED VIOLATION: On or about March 25 and April 2 and 5, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendants caused various quantities of the *seconal sodium capsules* to be repacked into unlabeled envelopes and sold without a prescription, which acts of the defendants resulted in the repackaged capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged capsules failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative has been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and the repackaged capsules failed to bear a label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged capsules bore no labeling containing directions for use.

DISPOSITION: May 18, 1950. Pleas of *nolo contendere* having been entered, the court imposed a fine of \$250 against each defendant.

3127. Misbranding of Gold-N-Medal Foot Balm. U. S. v. 6 Dozen Bottles, etc. (F. D. C. No. 27637. Sample No. 13668-K.)

LABEL FILED: August 10, 1949, Middle District of Pennsylvania.

ALLEGED SHIPMENT: On or about July 12, 1949, by the Golden Boy Distributing Co., from Brooklyn, N. Y., via the automobile of Edward N. Golden, the owner of the Golden Boy Distributing Co.

PRODUCT: 6 dozen 12-ounce bottles, 8 dozen 4-ounce bottles, and 2 dozen 2-ounce bottles, of *Gold-N-Medal Foot Balm* at Wilkes-Barre, Pa., in possession of the Golden Boy Distributing Co.

LABEL, IN PART: (Bottle) "The Gold-N-Medal Foot Balm Contains Lanolin, Stearic Acid, Camphor, Menthol, Methyl Salicylate And Eucalyptus Oil."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: June 12, 1950. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

3128. Adulteration of jalap root, angelica root, orrisroot, rue herb, and coltsfoot leaves. U. S. v. 11 Bags, etc. (F. D. C. No. 28307. Sample Nos. 10074-K to 10079-K, incl.)

LABEL FILED: November 21, 1949, Southern District of New York.

ALLEGED SHIPMENT: Between July 24, 1946, and February 23, 1949, imported from various foreign countries.

PRODUCT: 11 164-pound bags of *jalap root*, 7 110-pound bags and 38 100-pound bales of *angelica root*, 7 110-pound bags of *orrisroot*, 17 112-pound bales of *rue herb*, and 15 bales, each containing 111 kilos, of *coltsfoot leaves*, at New York, N. Y.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the articles consisted in whole or in part of filthy substances by reason of the presence of insects. The articles were adulterated while held for sale after shipment in interstate commerce.

DISPOSITION: December 29, 1949, and January 16, 1950. Max Van Pels, New York, N. Y., claimant for the *jalap root*, *orrisroot*, and the 7-bag lot of *angelica root*, and the Meer Corporation, New York, N. Y., claimant for the remainder of the products, having consented to the entry of decrees, judgments of condemnation were entered and the court ordered that the products be released under bond for segregation and destruction of the unfit portions. The segregation operations resulted in the destruction of 2,468 pounds of the products out of a total of 11,855 pounds which were seized.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3129. Adulteration and misbranding of Folamin. U. S. v. Injectables Research Corp. Plea of guilty. Fine, \$350. (F. D. C. No. 28125. Sample Nos. 15271-K, 41700-K, 42018-K, 42024-K, 43162-K, 58000-K, 58100-K.)

INFORMATION FILED: February 17, 1950, Southern District of Indiana, against the Injectables Research Corp., Indianapolis, Ind.

ALLEGED SHIPMENT: Between the approximate dates of November 1 and December 14, 1948, from the State of Indiana into the States of Illinois and Arizona.

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess. The article purported and was represented to be suitable and appropriate for intramuscular use, which use requires a sterile product, whereas the article was not sterile but was contaminated with viable micro-organisms.

Misbranding, Section 502 (a), the statements in the labeling of the article "Intramuscular," "Intramuscular Only," and "For Intramuscular Use Only" were false and misleading.

DISPOSITION: May 19, 1950. A plea of guilty having been entered, the court imposed a fine of \$350.

3130. Adulteration and misbranding of chorionic gonadotropin. U. S. v. 341 Vials * * *. (F. D. C. No. 28908. Sample No. 52392-K.)

LABEL FILED: March 28, 1950, Eastern District of Tennessee.

ALLEGED SHIPMENT: On or about January 17, 1950, from New York, N. Y.

PRODUCT: 341 vials of *chorionic gonadotropin* at Bristol, Tenn.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 10,000 units per vial.

Misbranding, Section 502 (a), the label statement "Chorionic Gonadotropin 10,000 Units Per Vial" was false and misleading as applied to the article, which contained not more than 5,000 International Units of chorionic gonadotropin per vial.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: June 28, 1950. Default decree of condemnation and destruction.

3131. Adulteration of chorionic gonadotropin. U. S. v. 110 Vials * * *. (F. D. C. No. 29073. Sample No. 73653-K.)

LABEL FILED: April 19, 1950, Eastern District of New York.

ALLEGED SHIPMENT: On or about January 24, 1950, by the Sylvana Chemical Co., from Orange, N. J.

PRODUCT: 110 vials of *chorionic gonadotropin* at Brooklyn, N. Y. The product was invoiced and guaranteed by the shipper as containing 5,000 International Units of chorionic gonadotropin. Examination showed that the product contained substantially less than that amount of chorionic gonadotropin.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess.

DISPOSITION: June 7, 1950. Default decree of condemnation and destruction.

3132. Adulteration and misbranding of chorionic gonadotropin. U. S. v. 51 Vials * * *. (F. D. C. No. 29079. Sample No. 80859-K.)

LABEL FILED: April 20, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about December 8, 1949, from Inglewood, Calif.

PRODUCT: 51 10-cc. vials of *chorionic gonadotropin* at Philadelphia, Pa.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported to possess, namely, 1,000 International Units of chorionic gonadotropin per cubic centimeter, after dilution to 10 cc.

Misbranding, Section 502 (a), the label statement "When reconstituted with 10 cc of * * * diluent each 1 cc will contain 1,000 I. U. of Chorionic Gonadotropin" was false and misleading as applied to the article, the potency of which, when diluted to 10 cc., was less than 1,000 International Units per cubic centimeter.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: June 12, 1950. Default decree of condemnation and destruction.

3133. Adulteration of Testramone. U. S. v. 87 Vials * * *. (F. D. C. No. 29085. Sample No. 73927-K.)

LIBEL FILED: April 27, 1950, Southern District of New York.

ALLEGED SHIPMENT: On or about March 21, 1950, by Harvey Laboratories, Inc., from Philadelphia, Pa.

PRODUCT: 87 10-cc. vials of *Testramone* at New York, N. Y.

LABEL, IN PART: "Testramone Intramuscular Injection of Vitamin B Complex."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess since it was for parenteral administration and was contaminated with living micro-organisms, whereas a drug for parenteral administration is sterile.

DISPOSITION: June 30, 1950. Default decree of condemnation. The court ordered that the product be delivered to the Food and Drug Administration.

3134. Adulteration and misbranding of adhesive bandages. U. S. v. 1,978 Cartons, etc. (F. D. C. No. 28975. Sample Nos. 77209-K, 77210-K.)

LIBEL FILED: April 19, 1950, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about March 16, 1950, by the Seamless Rubber Co., New Haven, Conn.

PRODUCT: 4,856 cartons, each carton containing 12 tins, and each tin containing 36 *adhesive bandages*, at St. Louis, Mo.

LABEL, IN PART: (Tin) "Quik-Bands Assorted With Mercurochrome Sterilized [or "Assorted Sterilized Plain"] * * * Adhesive Bandages"; (individual bandage) "Sterile."

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be "Adhesive Absorbent Gauze [or "Adhesive Absorbent Compress"]", a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its quality and purity fell below the official standard since it was not sterile.

Misbranding, Section 502 (a), the label statements "Sterile" and "Sterilized" were false and misleading as applied to an article which was not sterile.

DISPOSITION: April 28, 1950. The Seamless Rubber Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be released under bond to be brought into compliance with the law, under the supervision of the Federal Security Agency. The product was subsequently sterilized.

3135. Adulteration and misbranding of clinical thermometers. U. S. v. 22 Cartons * * *. (F. D. C. No. 29096. Sample No. 80968-K.)

LIBEL FILED: May 3, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about March 29, 1950, by the Hygrade Thermometer Co., from Brooklyn, N. Y.

PRODUCT: 22 cartons, each carton containing 12 boxes, and each box containing 1 *clinical thermometer*, at Philadelphia, Pa.

Examination of 24 samples showed that 6 failed to meet the hard shaker test prescribed by C. S. 1-32, i. e., failed to shake down to 96° F. or lower, and that 2 had engraved markings wider than the intervening space. C. S. 1-32 provides that the width of the marking shall not be more than one-half the length of the graduation interval.

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported or was represented to possess.

Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading as applied to the article, which failed to comply with the specifications as stated: (Leaflet in box) "Certificate of Accuracy for Clinical Thermometer * * * This test is governed by a Standard Thermometer which has been tested and approved by the Bureau of Standards, Washington, D. C. All our thermometers are manufactured in accord with their specifications. (C. S. 1-32 Department of Commerce.) * * *."

DISPOSITION: June 20, 1950. Default decree of condemnation and destruction.

3136. Adulteration and misbranding of clinical thermometers. U. S. v. 12 Dozen * * *. (F. D. C. No. 29036. Sample No. 7397-K.)

LIBEL FILED: March 31, 1950, Western District of Pennsylvania.

ALLEGED SHIPMENTS On or about November 8, 1949, by the Guardian Thermometer Co., from New York, N. Y.

PRODUCT: 12 dozen *clinical thermometers* at Erie, Pa.

Examination of 24 thermometers showed that 1 thermometer failed to meet the C. S. 1-32 test for entrapped gas; that 3 thermometers failed to meet the test for hard shakers; and that 1 thermometer out of 5 failed to meet the test for loss of pigment.

LABEL, IN PART: "Clinical Fever Thermometers Oral" and "Globe Fever Thermometer Oral."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the following statements in the labeling were false and misleading as applied to the article, which failed to comply with the specifications stated: (On 1-dozen container and individual carton) "This thermometer has been tested, found to comply with the requirements of the Department of Commerce Commercial Standard C. S. 1-32" and (on leaflet packaged with thermometer) "This Is To Certify That Self-registering Clinical Thermometer 'GT' has been examined, tested and found to meet all requirements and tests specified in the 'Commercial Standard C. S. 1-32 for Clinical Thermometers' used by the United States Department of Commerce."

DISPOSITION: June 2, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3137. Misbranding of W. E. & M. E. Herb Laxative. U. S. v. 94 Bottles * * *. (F. D. C. No. 29031. Sample No. 80909-K.)

LIBEL FILED: On or about April 6, 1950, District of New Jersey.

ALLEGED SHIPMENT: On or about February 27, 1950, by the W. E. & M. E. Herb Laxative Co., from Philadelphia, Pa.

PRODUCT: 94 4-ounce bottles of *W. E. & M. E. Herb Laxative* at Camden, N. J.

*See also Nos. 3121, 3129, 3130, 3132, 3134-3136.

LABEL, IN PART: “* * * W. E. & M. E. Herb Laxative Active Ingredients: Ragweed, White Oak Bark, Red Oak Bark, Golden Seal Root, Queen's Root, Gentian Root, Rhubarb, Black Snake Root, Virginia Snake Root, Gall of the Earth, Jamaica Ginger Root, Poke Root, Peppermint, Blood Root, Lily of the Valley, Rosemary, Buchu, Valarian Root, Dandelion Root, Cape Aloes, Senna Leaves, Mandrake.”

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular entitled “WE & ME Herb Tonic,” which was attached to each bottle of the article, were false and misleading. The statements represented and suggested that the article was a tonic and that it was effective in the treatment of arthritis, nervousness, liver and kidney trouble, lost pep, lost appetite, backache, lost memory, lost energy, neuritic conditions, lumbago, headache, indigestion, gas, pains, belching, heartburn, sour stomach, rheumatism, bladder trouble, colds, and dizziness. The article was not a tonic and was not effective in the treatment of the disease conditions stated and implied.

DISPOSITION: June 13, 1950. Default decree of condemnation and destruction.

3138. Action to enjoin and restrain the interstate shipment of a device known as Radiant Ozone Generator. U. S. v. J. C. Gage (Ozone Clinic). Consent decree granting injunction. (Injunction No. 213.)

COMPLAINT FILED: April 19, 1950, Western District of Missouri, against J. C. Gage, trading as the Ozone Clinic, Kansas City, Mo.

NATURE OF CHARGE: That the defendant had been and was at the time of filing the complaint, introducing and delivering for introduction into interstate commerce a device known as *Radiant Ozone Generator*, consisting of an electrical transformer, the primary lead of which was intended to be connected to an alternating current supply and each terminal of the secondary lead connected to one end of a series of gas-filled tubes similar to the so-called neon lights.

The device was alleged to be misbranded within the meaning of Section 502 (a), by reason of false and misleading statements in the labeling. The labeling included leaflets entitled “The Radiant Ozone Generator” and “How to Use the Radiant Ozone Generator For the Best Results at Home” and twenty-eight mimeographed pages of testimonials.

Certain statements in the labeling represented and suggested that the device would produce ozone, rays, color, and vibration, which, it was claimed, are the four essential things for health; that the device would relieve suffering from many incurable diseases, destroy all germs and bacteria, deodorize and purify the air, and purify the blood and rejuvenate the entire body; that the device would ozonize the body and assist one in getting the best results for various diseases; that it would revitalize the body; that it would be effective in aborting flu and pneumonia, maintaining and restoring health and strength, cleansing the blood, scattering blood clots, and killing germs in the blood; and that the device would be effective in the treatment of arthritis, asthma, anemia, cancer, diabetes, sinus infections, pneumonia, rheumatism, piles, varicose veins, neuritis, colds, tonsillitis, sore throat, headache, stomach ache, toothache, earache, indigestion, fever and grippe, angina, diphtheria, mumps, whooping cough, bladder disorders, eye trouble, catarrh, heart trouble, hay fever, liver trouble, prostate gland trouble, colitis, constipation, paralysis, rheumatism, ulcers, sores, sprains, tuberculosis, mastoid ear, throat troubles, chickenpox, cancer of the breast, inflammation of the kidneys, neuralgia, disease caused

by impure blood, ailments caused by poor circulation, enlarged heart, cataract, bronchial asthma, appendicitis, weakened run-down condition, sciatic rheumatism, and partial paralysis. The device when used in the manner suggested in its labeling, or in any other manner, would not be effective in the treatment of any of the diseases, or for the purposes, stated in the labeling.

The complaint alleged also that the false and misleading nature of the labeling of the device was aggravated by reason of the fact that the labeling recommended the device for the treatment of various incurable and serious diseases, such as cancer and diabetes, with the leaflet "How to Use the Radiant Ozone Generator For the Best Results at Home" specifically stating: "Do Not Use Medicine in Any Form When Using The Ozone Generator. This Means The Entire Time," whereas, if the device were used as suggested to the exclusion of any medicine, particularly in treating the incurable and serious diseases for which it was recommended, the health of the user would be seriously and permanently impaired, and death, as well as unbearable suffering, may well be the result.

The complaint alleged further that unless restrained, the defendant would continue to introduce and deliver for introduction into interstate commerce the misbranded device.

PRAYER OF COMPLAINT: That the defendant be perpetually enjoined from commission of the acts complained of, and that a preliminary injunction be granted during the pendency of the action.

DISPOSITION: April 19, 1950. The defendant having consented to the entry of a decree, the court issued an order permanently enjoining the defendant from directly or indirectly introducing or delivering for introduction into interstate commerce, the device in question or any similar device which was misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.

DRUGS FOR VETERINARY USE

3139. Misbranding of Sulfa-Col, Sulfa-Ton, Dia-Ton, Ry-Ton, Ton-It, and Kosa-Ton. U. S. v. Edward O. Sutherland (Kilz-Jerm Laboratory). Plea of guilty. Fine of \$200, plus costs. (F. D. C. No. 29110. Sample Nos. 43203-K to 43208-K, incl.)

INFORMATION FILED: April 27, 1950, Northern District of Ohio, against Edward O. Sutherland, trading as the Kilz-Jerm Laboratory, Toledo, Ohio.

ALLEGED SHIPMENT: Between the approximate dates of December 30, 1947, and October 5, 1948, from the State of Ohio into the State of Michigan.

PRODUCT: Analyses disclosed that the *Sulfa-Col* consisted of approximately 5 percent sulfathiazole in dilute hydrochloric acid; that the *Sulfa-Ton* consisted of approximately 4 percent sulfaguanidine in dilute hydrochloric acid; that the *Dia-Ton* consisted of 3.68 grams of benzalkonium chloride per 100 cc. solution; that the *Ry-Ton* consisted essentially of water, potassium dichromate, creosote, magnesium sulfate, and halogens; that the *Ton-It* consisted of a water solution of copper and iron compounds, with plant extractives and pungent principles, and a small amount of strychnine; and that the *Kosa-Ton* consisted of a red aqueous liquid containing, chiefly, acetic acid and epsom salt.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the articles were false and misleading since the articles when used as directed would not be efficacious for the purposes represented, and since the *Dia-Ton* was not nonpoisonous. The statements represented and suggested:

That the *Sulfa-Col* when used as directed would be efficacious to relieve the symptoms of coryza (colds) in chickens and turkeys;

That the *Sulfa-Ton* when used as directed would be efficacious to relieve the symptoms of coccidiosis in chickens and turkeys and to control cecal coccidiosis in chickens and turkeys;

That the *Dia-Ton* was nonpoisonous and when used as directed would be efficacious in the treatment of pasting in chickens and turkeys and scours in calves, and in the prevention and treatment of disease in baby chicks, baby poults, grown chickens, turkeys, and rabbits;

That the *Ry-Ton* would be efficacious to relieve in poultry the symptoms of colds and roup and the conditions implied by the abbreviation, "etc.";

That the *Ton-It* would be efficacious in the treatment and prevention of the symptoms of round worms in chickens, chicks, rabbits, and hogs;

That the *Kosa-Ton* would be efficacious in the treatment of the symptoms of coccidiosis in poultry, in the treatment and prevention of disease in chickens, and in the prevention of disease in rabbits.

DISPOSITION: May 1, 1950. A plea of guilty having been entered, the court imposed a fine of \$200 and costs.

3140. Misbranding of Arnold Eqworm Powder. U. S. v. 66 Jars * * *.
(F. D. C. No. 28722. Sample No. 1286-K.)

LIBEL FILED: February 20, 1950, Southern District of Florida.

ALLEGED SHIPMENT: On or about June 21, 1949, by Arnold Laboratories, from New Castle, Ind.

PRODUCT: 66 1-pound jars of *Arnold Eqworm Powder* at Miami, Fla.

LABEL, IN PART: "Arnold Eqworm Powder Contains: Arsenic Trioxide . . . 2% Powdered Worm Seed . . . 4% Tobacco Powder . . . 5% Powdered Areca Nut . . . 10% Copper Sulfate, Sodium Chloride, Iron Sulfate, Calcium Phosphate."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the article were false and misleading since they represented and suggested that the article was effective as a worm powder and was effective to reduce the intestinal infestations of ascarids and strongyles of horses and mules, whereas the article was not effective for such purposes.

DISPOSITION: June 8, 1950. Default decree of forfeiture and destruction.

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¹ (3138) Permanent injunction issued.

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¹ (3138) Permanent injunction issued.

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<i>Customs</i>	<i>Securities</i>
<i>Fair Trade Practice</i>	<i>Shipping</i>
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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3141-3160

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., November 1, 1950.

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*For presence of a habit-forming narcotic without warning statement, see Nos. 3142-3144; omission of, or unsatisfactory, ingredients statements, Nos. 3142, 3143, 3145, 3146; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3142-3147, 3159; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3142-3146; cosmetic, actionable under the drug provisions of the Act, No. 3156.

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS

3141. Misbranding of first aid kits. U. S. v. 118 Kits * * *. (F. D. C. No. 29094. Sample No. 80874-K.)

LIBEL FILED: May 2, 1950, Eastern District of Pennsylvania.

ALLEGED SHIPMENT: On or about October 6, 1949, by the All State Iron Scrap & Metal Co., from Middletown, Del.

PRODUCT: 118 first aid kits containing various items of drugs including, in each, an envelope of *sulfanilamide powder* (5 grams) and a package of 7.7 gr. *sulfadiazine tablets* (8 tablets), at Philadelphia, Pa. Some of the kits contained also a package of two tubes ($\frac{3}{4}$ -ounce size) of *tannic acid-sulfadiazine ointment* (sulfadiazine 5%).

These products could not be used safely and efficaciously in self-medication. They should be dispensed only on prescription, and they were in the hands of a dealer who was not authorized to fill prescriptions.

NATURE OF CHARGE: Misbranding, Section 502 (j), the products were dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in their labelings, as follows: (*Sulfanilamide powder*) "For Topical Use Warning—Absorption of this drug applied locally varies with the tissue and degree of injury but may be sufficiently great to cause systemic toxic reactions. Dyspnoea, vertigo, cyanosis, and methemoglobinemia are signs that indicate a reduction of dosage. Constant observation of the patient is essential. Caution: To be used only by or on the prescription of a physician," (*tannic acid-sulfadiazine ointment*) "For local application only not to be used on face, hands or genitals. Ointment is removable with water or saline solution * * * for U. S. Army Use Only," and (*sulfadiazine tablets*) "See back label for directions Caution—To be used only by or on the prescription of a physician. Warning—This is a dangerous drug which may cause serious or fatal injury unless taken under adequate and continuous medical supervision. Directions 1. If wounded, take two (2) tablets every five (5) minutes until all are taken. 2. It is important that you drink large quantities of water when taking the drug. 3. Caution—Do not take otherwise except under specific direction of Medical Officer."

DISPOSITION: June 22, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR
ADEQUATE DIRECTIONS OR WARNING STATEMENTS

3142. Misbranding of Benadryl capsules, Nembutal capsules, sulfonamides triplex tablets, Dexedrine sulfate tablets, and Seconal sodium capsules. U. S. v. Central Drug Co. and Harlan C. Bopp. Pleas of guilty. Fine of \$1,000 against each defendant. (F. D. C. No. 28124. Sample Nos. 45943-K, 45948-K, 45951-K, 45952-K, 45977-K, 45978-K, 45980-K, 45981-K, 45985-K.)

INFORMATION FILED: February 17, 1950, Eastern District of Illinois, against the Central Drug Co., a corporation, East St. Louis, Ill., and Harlan C. Bopp, president of the corporation.

INTERSTATE SHIPMENT: Between the approximate dates of June 3, 1948, and March 28, 1949, from the State of Missouri into the State of Illinois, of quantities of *Benadryl capsules*, *Nembutal capsules*, *sulfonamides triplex tablets*, *Dexedrine sulfate tablets*, and *Seconal sodium capsules*.

ALLEGED VIOLATION: On or about January 6, 19, and 21, March 29, and April 7, 11, and 13, 1949, while the drugs were being held for sale after shipment in interstate commerce, the Central Drug Co. and Harlan C. Bopp caused various quantities of the drugs to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged *Nembutal capsules* and *sulfonamides triplex tablets* failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents; and Section 502 (e) (2), the repackaged *sulfonamides triplex tablets* bore no label containing the common or usual name of each active ingredient, namely, sulfathiazole, sulfadiazine, and sulfamerazine.

Further misbranding, Section 502 (d), the *Nembutal capsules* and the *Seconal sodium capsules* contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, found to be, and by regulations designated as, habit forming; and when repackaged, their labels failed to bear the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged drugs, with the exception of the *sulfonamides triplex tablets*, failed to bear adequate directions for use in that the directions on the labeling of the *Seconal sodium capsules*, namely, "One as needed," were not adequate directions for use, and that the labeling of the *Nembutal capsules*, *Benadryl capsules*, and *Dexedrine sulfate tablets* bore no directions for use; and, Section 502 (f) (2), the repackaged *sulfonamides triplex tablets* bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: May 23, 1950. Pleas of guilty having been entered, the court imposed a fine of \$1,000 against each of the defendants.

3143. Misbranding of dextro-amphetamine phosphate tablets, sulfadiazine tablets, Tuinal capsules, Seconal sodium capsules, and Dexedrine sulfate Tablets. U. S. v. Weipert Drug Co., a corporation, and James V. Cockrum, Clyde Frick, and Alfred Hoffman. Plea of guilty for corporation; pleas of nolo contendere for individual defendants. Fine of \$2,000 against corporation; sentences suspended against individual defendants and these defendants placed on probation for 1 year. (F. D. C. No. 28141. Sample Nos. 60870-K, 60905-K, 60919-K, 60941-K, 60951-K, 60953-K, 60957-K, 60960-K.)

INFORMATION FILED: March 8, 1950, Eastern District of Missouri, against the Weipert Drug Co., a corporation, St. Louis, Mo., and against James V. Cockrum, secretary and pharmacist, and Clyde Frick and Alfred Hoffman, pharmacists, for the corporation.

INTERSTATE SHIPMENT: From the States of New York, Indiana, and Pennsylvania, into the State of Missouri, of quantities of *dextro-amphetamine phosphate tablets*, *sulfadiazine tablets*, *Tuinal capsules*, *Seconal sodium capsules*, and *Dexedrine sulfate tablets*.

ALLEGED VIOLATION: On or about June 14, July 7, and August 9, 19, 21, 22, and 23, 1949, while a number of the above-mentioned tablets and capsules were being held for sale at the Weipert Drug Co. after shipment in interstate commerce, various quantities of the tablets and capsules were repacked and sold without a prescription, which acts resulted in the repackaged tablets and capsules being misbranded. The Weipert Drug Co. and James V. Cockrum were charged with causing the acts of repacking and sale of the drugs involved in each of the eight counts of the information; and, in addition, Alfred Hoffman, in three of the counts, and Clyde Frick, in one of the counts, were charged with causing such acts to be done in connection with the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged *dextro-amphetamine phosphate tablets*, *sulfadiazine tablets*, *Dexedrine sulfate tablets*, and a portion of the repackaged *Seconal sodium capsules* bore no label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the repackaged drugs bore no label containing a statement of the quantity of the contents; and Section 502 (e) (1), the repackaged *dextro-amphetamine phosphate tablets* failed to bear a label containing the common or usual name of such tablets, namely, dextro-amphetamine phosphate.

Further misbranding, Section 502 (d), the *Tuinal capsules* and *Seconal sodium capsules* contained chemical derivatives of barbituric acid, which derivatives had been by the Administrator of the Federal Security Agency, after investigation, found to be, and by regulations designated as, habit forming; and when repackaged, failed to bear labels containing the name, and quantity or proportion of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of each of the repackaged drugs failed to bear adequate directions for use since the directions on the labeling of the repackaged *Tuinal capsules* and on the labeling of a portion of the *Seconal sodium capsules*, namely, "One as needed," were not adequate directions for use, and since the labeling of a portion of the *seconal sodium capsules* and the labeling of the *dextro-amphetamine phosphate tablets*, *sulfadiazine tablets*, and *Dexedrine sulfate tablets* bore no directions for use; and, Section 502 (f) (2), the repackaged *dextro-amphetamine phosphate tablets* and *sulfadiazine tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 5, 1950. A plea of guilty was entered on behalf of the corporation and a plea of nolo contendere was entered on behalf of each individual defendant. The court thereupon imposed a fine of \$2,000 against the corporation, suspended the imposition of sentences against the individual defendants, and placed the individual defendants on probation for 1 year.

3144. Misbranding of *Seconal sodium capsules*, *pentobarbital sodium capsules*, and *sulfadiazine tablets*. U. S. v. Robert E. Thacker (Thacker Drug Store). Plea of nolo contendere. Fine, \$300. (F. D. C. No. 29109. Sample Nos. 55142-K, 55143-K, 55145-K, 55146-K, 55151-K, 55153-K.)

INFORMATION FILED: May 2, 1950, Western District of Oklahoma, against Robert E. Thacker, trading as the Thacker Drug Store, at Grandfield, Okla.

INTERSTATE SHIPMENT: From the States of Indiana and Missouri, of quantities of *Seconal sodium capsules*, *pentobarbital sodium capsules*, and *sulfadiazine tablets*.

ALLEGED VIOLATION: On or about March 23, 1949, while a number of *Seconal sodium capsules* were being held for sale after shipment in interstate commerce, the defendant caused the capsules to be sold and disposed of to a purchaser, in the original bottle in which the capsules had been shipped in interstate commerce, without a prescription of a physician. The capsules contained in the original bottle had been exempt from the requirements of Section 502 (f) (1), prior to the date of the sale, since the label bore the prescription legend required by the regulations. This exemption expired when the defendant sold the capsules without a physician's prescription and resulted in the misbranding of the capsules in violation of Section 502 (f) (1), since the bottle bore no labeling containing directions for use.

On or about February 18, March 22, and May 2 and 6, 1949, the defendant caused a number of *Seconal sodium capsules*, *pentobarbital sodium capsules*, and *sulfadiazine tablets* to be repackaged and sold to various persons without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded as follows: Section 502 (b) (1), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the repackaged drugs bore no labels containing accurate statements of the quantity of the contents; Section 502 (d), the repackaged *Seconal sodium capsules* and *pentobarbital sodium capsules* contained chemical derivatives of barbituric acid, which derivatives had been designated as habit forming, and the repackaged capsules bore no labels containing the name and quantity of such derivatives and in juxtaposition therewith the statement "Warning—May be habit forming"; Section 502 (f) (1), the labeling of the repackaged drugs bore no directions for use; and, Section 502 (f) (2), the labeling of the repackaged *sulfadiazine tablets* bore no warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: May 22, 1950. A plea of *nolo contendere* having been entered, the court imposed a fine of \$300.

3145. Misbranding of sulfadiazine tablets and sulfathiazole tablets. U. S. v. Howard B. Ridley and Albert G. Nickleberry. Pleas of *nolo contendere*. Fine of \$250 against each defendant. (F. D. C. No. 28153. Sample Nos. 32074-K, 34121-K, 34162-K.)

INFORMATION FILED: April 19, 1950, Northern District of California, against Howard B. Ridley, a partner in the partnership of Center Pharmacy, Oakland, Calif., and Albert G. Nickleberry, a pharmacist for the partnership.

INTERSTATE SHIPMENT: From North Chicago, Ill., and Indianapolis, Ind., into the State of California, of quantities of *sulfathiazole tablets* and *sulfadiazine tablets*.

ALLEGED VIOLATION: On or about January 13 and April 25 and 28, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1), and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; Section 502 (e) (1), the repackaged drugs failed to bear labels containing the common or usual names of the drugs; Section 502 (f) (1), the repackaged drugs failed to bear labeling containing directions for use; and, Section 502 (f) (2), the repackaged drugs bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 9, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$250 against each defendant.

3146. Misbranding of sulfathiazole tablets and Dexedrine sulfate tablets. U. S. v. J. Howard Luna (H. & W. Drug Co.), and Thomas C. Lawson. Pleas of guilty. Fine of \$100 against each defendant. (F. D. C. No. 28126. Sample Nos. 53391-K, 53392-K, 53474-K, 53499-K, 53500-K.)

INFORMATION FILED: March 14, 1950, Northern District of Alabama, against J. Howard Luna, trading as the H. & W. Drug Co., Tuscaloosa, Ala., and against Thomas C. Lawson, a pharmacist employed by Mr. Luna.

INTERSTATE SHIPMENT: From the States of Indiana and Pennsylvania into the State of Alabama, of quantities of *sulfathiazole tablets* and *Dexedrine sulfate tablets*.

ALLEGED VIOLATION: On or about May 13 and June 28, 1949, and while the drugs were being held for sale after shipment in interstate commerce, the defendants, J. Howard Luna and Thomas C. Lawson, jointly caused various quantities of *sulfathiazole tablets* and *Dexedrine sulfate tablets* to be repackaged and sold without a prescription; and on or about June 28, 1949, J. Howard Luna individually caused similar sales of other quantities of the same drugs, which acts of the defendants resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged tablets failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; Section 502 (e) (1), certain quantities of the repackaged tablets failed to bear labels containing the common or usual name of the drug; Section 502 (f) (1), the labeling of the repackaged *Dexedrine sulfate tablets* bore no directions for use; and, Section 502 (f) (2), the repackaged *sulfathiazole tablets* bore no labeling containing warnings against use in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: May 8, 1950. Pleas of guilty having been entered, the court imposed a fine of \$100 against each defendant.

3147. Misbranding of Bible Way Tonic, Bible Way Anointing Oil, and drug capsules. U. S. v. Ray McDaniel (Elder R. McDaniel). Plea of guilty. Fine of \$50 and sentence of 1 year in jail on each of 4 counts. Jail sentence suspended and defendant placed on probation for 4 years. (F. D. C. No. 26728. Sample Nos. 1080-K, 19595-K, 19596-K.)

INFORMATION FILED: August 19, 1949, Southern District of Ohio, against Ray McDaniel, trading as Elder R. McDaniel, Columbus, Ohio.

ALLEGED SHIPMENT: On or about November 24 and 29, 1948, from the State of Ohio into the States of Florida and Tennessee.

PRODUCT: Analysis disclosed that the *Bible Way Tonic* was a dark red hydro-alcoholic liquid flavored with peppermint, containing chiefly plant extractives, including emodin-bearing drugs; that the *Bible Way Anointing Oil* consisted essentially of mineral oil and turpentine; and that the *drug capsules* contained salt and plant extractives.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the bottle label and in the circular entitled "In God We Trust" accompanying the *Bible Way Tonic* and certain statements on the bottle label of the *Bible Way Anointing Oil* were false and misleading. These statements represented and suggested that the *Bible Way Tonic* would be efficacious in the cure, mitigation, and treatment of tuberculosis, asthma, rheumatism, arthritis, high blood pressure, syphilis, sores, low blood pressure, and bronchial asthma, and would be efficacious as a building tonic for run-down conditions; and that the *Bible Way Anointing Oil* would be efficacious in the cure, mitigation, and treatment of aching muscles, arthritis, neuritis, rheumatic pains, and other human body pains. The articles would not be efficacious for the purposes represented.

Further misbranding, Section 502 (b) (2), the *Bible Way Tonic*, the *Bible Way Anointing Oil*, and the *drug capsules* failed to bear labels containing accurate statements of the quantity of the contents; and, Section 502 (f) (1), the labeling of the *drug capsules* failed to bear adequate directions for use in that there was no statement in the labeling of any condition, disease, or function for which the capsules were to be used.

DISPOSITION: May 22, 1950. A plea of guilty having been entered, the court imposed a total fine of \$200 and sentenced the defendant to serve one year in jail on each of the four counts of the information. The jail sentence was suspended and the defendant was placed on probation for four years, conditioned that he no longer engage in the drug business in any manner.

3148. Misbranding of Sun-O-Ray Compound and Sun-O-Ray Inhalator. U. S. v. George R. Thurman (Sun-O-Ray Products). Plea of nolo contendere. Fine of \$10, plus costs, and sentence of 1 hour in custody of United States marshal. (F. D. C. No. 28146. Sample Nos. 46440-K, 46521-K.)

INFORMATION FILED: March 30, 1950, Eastern District of Missouri, against George R. Thurman, trading as Sun-O-Ray Products, St. Louis, Mo.

INTERSTATE SHIPMENT: On or about January 17, 1949, from the State of Illinois into the State of Missouri.

ALLEGED VIOLATION: Between the approximate dates of January 28 and 31, 1949, while the articles were held for sale after shipment in interstate commerce, the defendant prescribed, recommended, and suggested, by oral statements to the public, uses of the articles in combination and use of the *Sun-O-Ray Compound* singly for various diseases, symptoms, and conditions for which adequate directions for use did not appear in the labeling, which acts of the defendant resulted in the articles being misbranded.

LABEL, IN PART: "Sun-O-Ray Inhalator Directions: Drop Sun-O-Ray fluid into large end of inhalator until cotton is moist. Inhale vapor by placing small end of tube to one nostril at a time, keeping other nostril closed. Use as required. Add more Sun-O-Ray every few days as needed" and "Sun-O-Ray Compound Directions: As a Liniment: Rub and massage well over the skin, where there is soreness or pain due to minor causes. As an inhalation:

A few drops in a basin of hot water, inhaled deeply, will bring relief from stuffed-up head, accompanying colds. In the Inhalator: The use of this preparation before retiring aids comfortable breathing * * * Sun-O-Ray Products 8323 So. Crandon Ave. Chicago 17, Ill."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles failed to bear adequate directions for use in the prevention and treatment of sinusitis, arthritis, weak eyes, pyorrhea, bad tonsils, catarrh, colds, infection of the eyes, running of the ears, loss of teeth, polio, and tuberculosis, in the lubrication of the eyes and joints, and in the killing of germs and purification of the air, which were the diseases, symptoms, conditions, and purposes for which the articles were prescribed, recommended, and suggested by the defendant as stated above.

DISPOSITION: May 10, 1950. Following the removal of the criminal proceedings against the defendant to the Northern District of Illinois for the entry of a plea, a plea of nolo contendere was entered and the court imposed a fine of \$10 and costs, and sentenced the defendant to serve 1 hour in the custody of the United States marshal.

3149. Misbranding of Spectro-Chrome. U. S. v. 1 Device * * * (and 26 other seizure actions). (F. D. C. Nos. 16788, 16789 to 16791, incl., 16820 to 16822, incl., 16824, 16827, 16836, 16903 to 16906, incl., 16920, 17017, 17020, 17270 to 17272, incl., 17276, 17279, 17679, 18139, 18140, 18829, 18888. Sample Nos. 3227-H, 4094-H, 4145-H, 4157-H, 4173-H, 4176-H to 4178-H, incl., 4848-H, 16305-H, 16307-H, 16309-H, 16313-H to 16317-H, incl., 16334-H, 16336-H, 16347-H, 16348-H, 16910-H, 16911-H, 17395-H to 17399-H, incl.)

LIBELS FILED: Between July 16, 1945, and January 31, 1946, Eastern District of Wisconsin, Eastern District of Pennsylvania, and Eastern District of Virginia.

ALLEGED SHIPMENT: Between the early part of 1943 and November 11, 1945, by Dinshah P. Ghadiali, from Newfield, N. J.

PRODUCT: 27 *Spectro-Chrome* devices at Milwaukee, West Bend, Racine, Sheboygan, Barton, Sheboygan Falls, and Hartford, Wis.; Egypt, Pa.; and Portsmouth, Va.

Examinations showed that the device consisted essentially of a cabinet equipped with an electric light bulb, an electric fan, a container for water, glass condenser lenses, and glass slides, each of a different color. The cabinet had an opening in the front in which the glass slides could be inserted and through which the light from the bulb would emit.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of each device were false and misleading. The statements on the labels of some of the devices represented and suggested that the devices were capable of measuring and restoring human radioactive and radioemanative equilibrium (normalization of imbalance) by attuned color waves; and the statements on the label of other devices represented and suggested that the devices were capable of restoring, maintaining, or otherwise favorably influencing the health of the user. The devices were incapable of measuring and restoring human radioactive and radioemanative equilibrium (normalization of imbalance) by attuned color waves since the devices were incapable of performing any function of measurement; there is in the human system no radioactive or radioemanative equilibrium; the use of color waves would have no effect on normal-

ation of imbalance; the devices were incapable of restoring, maintaining, or otherwise favorably effecting the health of the user; and use of color waves would have no effect on health.

Further misbranding, Section 502 (a), certain statements in the printed and graphic matter accompanying a number of the devices were false and misleading. The statements represented and suggested that the device when used as directed would be efficacious in the cure, mitigation, treatment, and prevention of all disorders of the heart, lungs, skin, nutrition, mentality, emotions, inflammation, disorders with pain, with swelling, with fever, or with redness, disorders of the blood, genitals, females, children, teeth, motor system, sensory system, gonorrhea, syphilis, ulcers, chancres, smallpox, scarlet fever, diphtheria, whooping cough, chicken pox, measles, German measles, mumps, fallen womb, habitual tendency to miscarriage, burns of any degree, sunstroke, diabetes, sex frigidity, accident, dog bite, eye disorder, ear abscess, mastoiditis, constipation, colds, gastritis, nervousness, ophthalmitis, rectal abscess, high blood pressure, poor circulation, tuberculosis, piles, varicose veins, aphonia, headache, hay fever, dizziness, sleeplessness, rash, poison ivy, stomach ulcers, sciatica, tachycardia, nose bleeding, lung hemorrhage, leg ulcer, prostate disorder, kidney disorder, tonsillitis, pleurisy, appendicitis, gout, pneumonia, removal of tumors, leaky heart, hiccoughs, arthritis, rheumatism, cataract, and X-ray and radium destruction; that the article would be effective in the control of cancerous growths, removal of certain types of blindness and deafness, and normalization of refractory carbuncles; that the device was a liver energizer, hemoglobin builder, respiratory stimulant, parathyroid depressant, thyroid energizer, antispasmodic, galactagogue, antirachitic, emetic, stomachic, lung builder, motor stimulant, alimentary tract energizer, lymphatic activator, splenic depressant, digestant, cathartic, cholagogue, anthelmintic, nerve builder, cerebral stimulant, thymus activator, antacid, chronic alterative, antiscorbutic, laxative, expectorant, bone builder, pituitary stimulant, disinfectant, purificatory, antiseptic, germicide, bactericide, detergent, muscle and tissue builder, cerebral depressant, acute alterative, tonic, skin builder, antipruritic, diaphoretic, febrifuge, counterirritant, anodyne, demulcent, vitality builder, parathyroid stimulant, thyroid depressant, respiratory depressant, astringent, sedative, pain reliever, hemostatic, inspissator, phagocyte builder, splenic stimulant, cardiac depressant, lymphatic depressant, leucocyte builder, venous stimulant, renal depressant, antimalarial, vasodilator, anaphrodisiac, narcotic, antipyretic, analgesic, sex builder in supernormal, suprarenal stimulant, cardiac energizer, diuretic, emotional equilibrator, auric builder, arterial stimulant, renal energizer, genital excitant, aphrodisiac, emmenagogue, vasoconstrictor, ecboic, sex builder in subnormal and other diseases, conditions, symptoms, and disorders; and that the device when so used as directed would constitute a safe and appropriate treatment. The device when used in accordance with the directions for use, or when used in any manner whatsoever, was of no value in the cure, mitigation, treatment, or prevention of any disease, disorder, condition, or symptom, and was of no value in affecting the structure, or any functions, of the body of man, and when so used as directed, may delay appropriate treatment of serious diseases, resulting in serious or permanent injury, or death to the user.

Further misbranding, Section 502 (f) (1), the labeling of one of the devices failed to bear adequate directions for use since it bore no directions for use.

DISPOSITION: Between October 23, 1945, and October 11, 1946. The consignees of 21 of the devices were Rose Regar, Edw. J. Schwalbach, Jacob Leszczynski, Ella Minnie Severin, Josephine Wysocki, Emma Taves, Elsie Hegel, Geraldine M. Peter, Agnes Skalecki, Hedwig Bakula, Adam Spaeth, Emma A. Wuerker, Herman R. Leudtke, Lena Lambrecht, Anna Jessen, Lydia Thieme, Elsie Wilke, Alfred C. Taddey, William Endwig, Edw. T. Rippey, and Sophie Walkiewicz.

When the United States marshal first attempted to make seizure of the 21 devices, the consignees refused to surrender them. Accordingly, proceedings were instituted to compel the consignees to surrender their devices, and as a result of such proceedings, all of the consignees except Hedwig Bakula and Emma A. Wuerker complied. Hedwig Bakula and Emma A. Wuerker were cited for contempt, following the issuance of orders to show cause why their devices should not be surrendered and their subsequent refusal to comply with the orders of the court to surrender the devices. Hearings were held in the matter, and at their conclusion, Hedwig Bakula and Emma A. Wuerker adjudged guilty of contempt. Each was sentenced to pay a fine of \$100 and to be committed to the custody of the United States marshal for a period of 30 days, with the provision, however, that they could purge themselves of such contempt by delivering their devices to the marshal within 24 hours. Hedwig Bakula and Emma A. Wuerker thereupon surrendered their devices.

Following the surrender of the 21 devices held by the above-named consignees, opportunity to appear as claimants was afforded to these individuals, as well as to the consignees of the 6 other devices who had not opposed seizure. However, no claims for any of the devices were made, and, accordingly, judgments of condemnation were entered. The court ordered that one of the devices be delivered to the Food and Drug Administration and that the other devices be destroyed.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3150. Adulteration and misbranding of castor oil. U. S. v. The National Specialty Co. and William Hoyt Elliott. Pleas of *nolo contendere*. Fine of \$101 against defendants. (F. D. C. No. 26688. Sample No. 39494-K.)

INFORMATION FILED: April 18, 1949, Middle District of Tennessee, against The National Specialty Co., a corporation, Nashville, Tenn., and William Hoyt Elliott, president of the corporation.

ALLEGED SHIPMENT: On or about July 9, 1948, from the State of Tennessee into the State of Alabama.

LABEL, IN PART: "Nasco Brand Castor Oil."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, spirits of turpentine, had been substituted for *castor oil*.

Misbranding, Section 502 (a), the label statement "Castor Oil" was false and misleading since the article did not consist of *castor oil* but did consist of spirits of turpentine.

DISPOSITION: May 15, 1950. Pleas of *nolo contendere* having been entered, the court imposed a total fine of \$101 against the defendants.

*See also No. 3159 (veterinary preparation).

3151. Adulteration and misbranding of castor oil. U. S. v. William Hoyt Elliott (National Specialty Co.). Plea of nolo contendere. Fine, \$101. (F. D. C. No. 26689. Sample No. 23242-K.)

INFORMATION FILED: April 18, 1949, Middle District of Tennessee, against William Hoyt Elliott, trading as the National Specialty Co., Nashville, Tenn.

ALLEGED SHIPMENT: On or about October 20, 1947, from the State of Tennessee into the State of Louisiana.

LABEL, IN PART: "Nasco Brand Castor Oil."

NATURE OF CHARGE: Adulteration, Section 501 (d) (2), a substance, spirits of turpentine, had been substituted for *castor oil*.

Misbranding, Section 502 (a), the label statement "Castor Oil" was false and misleading since the article did not consist of *castor oil* but did consist of spirits of turpentine.

DISPOSITION: May 15, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$101.

3152. Adulteration and misbranding of Vitramone and A-Vee. U. S. v. 87 Vials, etc. (F. D. C. No. 29317. Sample Nos. 73928-K, 73929-K.)

LIBEL FILED: May 17, 1950, Southern District of New York.

ALLEGED SHIPMENT: On or about March 21, 1950, by Harvey Laboratories, Inc., from Philadelphia, Pa.

PRODUCT: 87 vials of *Vitramone* and 93 vials of *A-Vee* at New York, N. Y. Examination showed that the products contained less than the declared amount of riboflavin.

LABEL, IN PART: (Vial) "1-10 cc. Ampul-Vial Vitramone * * * Intramuscular Injection of Vitamin B Complex * * * Each cc. contains: * * * Riboflavin 2 Mg." and (vial) "1-10 cc. Ampul-Vial A-Vee Sterile solution for parenteral use containing Vitamin B-Complex factors * * * Each cc. contains: * * * Riboflavin 2 Mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the articles fell below that which they purported and were represented to possess, namely, 2 mg. of riboflavin per cc.

Misbranding, Section 502 (a), the statements on the labels of the articles "Each cc. contains: * * * Riboflavin 2 Mg. * * *" were false and misleading.

DISPOSITION: June 22, 1950. Default decree of condemnation. The court ordered that the products be delivered to the Food and Drug Administration.

3153. Adulteration and misbranding of hydrogen peroxide. U. S. v. 39 Dozen Bottles * * *. (F. D. C. No. 28966. Sample No. 76410-K.)

LIBEL FILED: April 13, 1950, Eastern District of Arkansas.

ALLEGED SHIPMENT: On or about December 8, 1949, and January 17, 1950, from St. Louis, Mo.

PRODUCT: 39 dozen bottles of *hydrogen peroxide* at Little Rock, Ark.

NATURE OF CHARGE: Adulteration, Section 501 (b), the article purported to be and was represented as a drug, "Solution of Hydrogen Peroxide," the name

of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard since it contained less than 2.5 grams hydrogen peroxide in each 100 cc.

Misbranding, Section 502 (a), the label statement "Contains 3% Hydrogen Peroxide" was false and misleading as applied to an article which contained less than 3 percent hydrogen peroxide.

The article was adulterated and misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: June 12, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3154. Misbranding of Gramer's Sulgly-Minol. U. S. v. 79 Bottles * * *.
(F. D. C. No. 28704. Sample Nos. 54749-K, 54750-K.)

LIBEL FILED: On or about February 21, 1950, Northern District of Texas; amended libel filed on or about March 14, 1950.

ALLEGED SHIPMENT: On or about September 13, 1949, by the Walter W. Gramer Co., from Minneapolis, Minn.

PRODUCT: 79 4-ounce bottles of *Gramer's Sulgly-Minol* at Fort Worth, Tex., together with a number of leaflets entitled "Walter W. Gramer Co. Manufacturers of Gramer's Sulgly-Minol," a number of leaflets entitled "Arthritis . . . Hundreds Claim It's Grip Broken," and a number of circulars entitled "A Light Should Not Be Hidden—Testimonials."

LABEL, IN PART: (Bottle) "Gramer's Sulgly-Minol A Solution of Sulphur, Glycerine, Sulphurated Lime and Isopropyl Alcohol 6%."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the leaflets were false and misleading since the statements represented and suggested that the article was effective as a treatment, cure, and prevention for rheumatism and arthritis conditions, and as a treatment for boils and acne, whereas the article was not effective for such purposes.

DISPOSITION: June 29, 1950. Default decree of condemnation. The court ordered the drug, leaflets, and circulars destroyed.

3155. Misbranding of Gramer's Sulgly-Minol. U. S. v. 23 Bottles * * *.
(F. D. C. No. 29334. Sample No. 71499-K.)

LIBEL FILED: May 25, 1950, Southern District of California.

ALLEGED SHIPMENT: On or about April 1 and May 1, 1950, by the Radiant Health Products, from Bellingham, Wash.

PRODUCT: 23 4-ounce bottles of *Gramer's Sulgly-Minol* at Los Angeles, Calif., together with copies of a leaflet entitled "Arthritis . . . Hundreds Claim It's Grip Broken" and a copy of a circular entitled "A Light Should Not Be Hidden."

LABEL, IN PART: (Bottle) "Gramer's Sulgly-Minol A solution of Sulphur, Glycerine, Sulphurated Lime and Alcohol 6%."

*See also Nos. 3147, 3149-3153.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the leaflet and circular were false and misleading since the statements represented and suggested that the article was effective as a treatment, preventive, and cure for rheumatism and arthritis conditions, and as a treatment for boils and acne, whereas the article was not effective for such purposes.

DISPOSITION: June 16, 1950. Default decree of condemnation and destruction.

3156. Misbranding of McLaran's 3 out of 5. U. S. v. 52 Dozen Jars, etc. (F. D. C. No. 24889. Sample No. 9189-K.)

LABEL FILED: June 15, 1948, District of New Jersey.

ALLEGED SHIPMENT: On or about April 21 and 26 and May 4, 1948, by International 3 out of 5 Co., Ltd., from New York, N. Y.

PRODUCT: 52 dozen jars of *McLaran's 3 out of 5* at Asbury Park, N. J., together with a number of reprints from various magazines, a number of streamers entitled "Bring New Ambition to Your Scalp," and a number of counter display cards entitled "Here's the way to Bring New Ambition to Your Scalp" and "McLaran's 3 out of 5."

Examination showed that the product consisted essentially of lanolin, pumice, and a perfume material.

LABEL, IN PART: (Jar) "McLaran's 3 out of 5 For the Scalp Net Weight 3 Ounces."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the jar labels, display cartons, reprints from magazines, streamers, and counter display cards were false and misleading. The statements represented and suggested that the article was effective in growing hair in 3 out of 5 cases. The article was not effective to grow hair.

DISPOSITION: June 27, 1950. McLaran's 3 out of 5 For the Scalp, Inc., New York, N. Y., having appeared as claimant and later having withdrawn its claim, and Slav J. Youcheff, New York, N. Y., having subsequently filed a claim and answer in the case and having subsequently withdrawn his answer and consented to the entry of a decree, judgment of condemnation was entered. The court ordered that the product be destroyed.

3157. Misbranding of Ferguson's Zerret Applicator. U. S. v. William R. Ferguson (Ferguson's Zerret Applicator), and Mary A. Stanakis. Pleas of not guilty. Tried to the court and jury. Verdict of guilty. Sentence of 2 years in jail against William R. Ferguson and 1 year in jail against Mary A. Stanakis. (F. D. C. No. 25582. Sample Nos. 70216-H, 14906-K, 25863-K.)

INFORMATION FILED: March 31, 1949, Northern District of Illinois, against William R. Ferguson, trading as Ferguson's Zerret Applicator, Chicago, Ill., and Mary A. Stanakis.

ALLEGED SHIPMENT: On or about May 6 and November 18, 1947, and July 8, 1948, from the State of Illinois into the States of Wisconsin and South Dakota.

PRODUCT: This product was a dumbbell-shaped plastic device. Three of the devices were dismantled, and at the time of examination, one was found to contain only cotton and paraffin in the interior; one contained only dry cotton; and the third was filled with water, with a solids content somewhat greater than the published solids content of Chicago city water. The user was directed

to grasp the device by both hands in order to obtain the alleged beneficial effects.

LABEL, IN PART: (Leaflet) "Why Zerret Works Zerret is produced by expanding the hydrogen Atom, which in turn produces positive Life Energy. When you hold the Zerret Applicator it works on your life current, expanding the Atoms of the same. As this takes place, it in turn expands all atoms of your being."

NATURE OF CHARGE: Misbranding, Section 502 (a), the labeling of the device contained statements which were false and misleading since the device would not be efficacious for the purposes and would not fulfill the promises of benefit suggested and implied by the statements. The labeling of the device consisted of a number of circulars entitled "The Therapeutic Potency of Expanded Hydrogen Atoms" and "Ferguson's Zerret-Applicator" and a number of leaflets entitled "Directions for the Use of the Zerret Applicator" and "Why Zerret Works." The false and misleading statements in such labeling represented and suggested that the device would give health through the hands; that relaxation would take place throughout one's being with the use of the device; that the device would enable one to start getting well; that it would work on every atom of one's being; that its use would result in an expansion of the atoms of one's being; that its use would produce complete relaxation and a form of healing; that it was the key to the correction of disease; that anyone suffering from any known disease could become free from such suffering by using the device; that the device would enable one to get well and enjoy good health; that it would be efficacious in the treatment of human ailments and in the restoration and maintenance of health; that it would improve the flow of nervous energy and the circulation of body fluids in and through the body tissues; that the device would increase functioning power; that by its use the original force which activates every life form would be conducted into the body; that it would correct obesity and abnormal thinness due to glandular malfunctioning; that its use would enable persons with excess weight to reduce their appetite, and those with less than normal weight to increase their appetite and weight; that the device would provide a natural healing force; that it would introduce into the body the energy given off by expanded hydrogen atoms; that it would be efficacious in the treatment of diarrhea and constipation; that it would correct soft tissue overcontractions, fluid congestion and abnormalities of blood composition, and collections of waste materials in the body; that the device would reverse the aging processes and would cause a return to more youthful function, freedom, and mental outlook; that it would enable one to draw upon the inexhaustible supply of atomic energy and to flood the body with that rejuvenating force; that it would be efficacious in waste removal and in renormalization of function; and that the device would enable one to regain and retain mental and physical vigor far beyond the age when such vigor is ordinarily on the wane.

DISPOSITION: Pleas of not guilty having been entered on behalf of the defendants, the case came on for trial before the court and jury on May 10, 1950. The trial was concluded on May 17, 1950, at which time the jury returned a verdict of guilty against each defendant. A motion for a new trial was filed on behalf of the defendants on May 18, 1950, and was denied on May 22, 1950. On the latter date, the court imposed jail sentences of 2 years against William R. Ferguson and 1 year against Mary A. Stanakis.

3158. Misbranding of Pol-Izer. U. S. v. Otto W. Dressler (Gold Seal Laboratories). Plea of not guilty. Tried to the court. Verdict of guilty. Fine, \$100. (F. D. C. No. 26691. Sample No. 43462-K.)

INFORMATION FILED: April 23, 1949, District of Minnesota, against Otto W. Dressler, trading as the Gold Seal Laboratories, Minneapolis, Minn.

ALLEGED SHIPMENT: On or about September 8, 1948, from the State of Minnesota into the State of Indiana.

PRODUCT: Examination disclosed that the product was a device consisting of mercury sealed in a glass bulb which was cemented to a metal cylinder. When the device was swirled, it generated a weak electrostatic charge.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circulars entitled "The Pol-Izer (Miracle of the Age) Why Suffer" and "Pol-Izer Miracle of the Age The Results from its Use are Miraculous," which circulars accompanied the device, were false and misleading since the device would not be efficacious for the purposes represented and would not fulfill the promises of benefit stated and implied. The statements represented and suggested that the device would be efficacious in the cure, mitigation, and treatment of arthritis, sinusitis, eczema, constipation, hay fever, ulcers, diabetes, asthma, and anemia; that it would tend to normalize any part of the body which it contacted; that it would be efficacious in the cure, mitigation, and treatment of adhesion pains, arthritis pains, athlete's foot, high blood pressure, low blood pressure, head colds, indigestion, insomnia (nervousness), lumbago, migraine headaches, nervous stomach, bruises, burns, catarrh, colitis, cuts, dandruff, encephalitis (sleeping sickness), enuresis (bed wetting), falling hair, gastritis, goiters, fast heart, slow heart, leaky heart, strained heart, weak heart, angina pectoris, neuralgia, neurasthenia, neuritis, prostate gland trouble, rheumatism, scalds, sciatica, shaking palsy, sinus trouble, stomach gas, stomach ulcers, stuttering, toxemia, varicose veins, many additional ailments, and functional nutritional diseases; that the device would be efficacious in controlling the nervous, circulatory, respiratory, muscular, secretory, and excretory systems; that it would be efficacious as a regulator of functions and distributor of harmony; that it would be successful in improving nervous stomach, asthma, and diabetes; that constipation not due to intestinal obstruction could be controlled easily through use of the device, and that many other functional ailments could be relieved; that the five senses, seeing, hearing, feeling, tasting, and smelling, would be made keener by drinking water treated with the device; that the device would change the oxygen in water into ozone; that water treated with the device would be efficacious in the cure, mitigation, and treatment of stomach ulcers, gastritis, colitis, inflamed bladder, inflamed kidneys, sinusitis, and many other ailments of an inflammatory nature; that water treated with the device was a germicide and would kill many kinds of bacteria and germs, including the dandruff germ, as well as the fungi that causes athlete's foot; that water treated with the device would make an excellent remedy for hay fever, head colds, sinusitis, catarrh, and coughs; that use of water treated with the device would soothe the sores and stop the itching of eczema; that the device would make hard water soft; that it would remove the caffeine bitterness from coffee and the theine bitterness from tea; that it would greatly enrich the flavor of milk and would affect the taste of all beverages; that it would be efficacious for the relief of ailments that could not be relieved by a doctor, chiropractor, or osteopathic physician; that it would be efficacious in the treatment of many so-called incurable ailments; that it would relieve pains, mi-

graine headaches, and neuritic pains; that water treated with the device would be efficacious in the cure, mitigation, and treatment of a nervous stomach, and in the prevention of diseases, including colds; that water treated with the device would tend to normalize the digestive organs and enable the organs to extract more nourishment, especially the various vitamins and minerals, from food; that water treated with the device would enable the body to assimilate more vitamin A from food and thereby build resistance to infections, increase vitality, and improve eyesight; that water treated with the device would have a salutary effect upon the nervous system and would enable the body to absorb more vitamin B₁ from the food, resulting in a more invigorated feeling, better appetite, and the relief of many nervous disorders; that liquids treated with the device would enable one to make use of, and benefit from, the vitamins in food to a much greater extent; that the device when used in conjunction with water treated with the device, would be efficacious for the alleviation of pains, the correction of varicose veins, and the removal of goiters; that water treated with the device would be efficacious in overcoming food allergy and would improve one's digestive organs; that the device when used in conjunction with water treated with the device, would be efficacious in the cure, mitigation, and treatment of adhesion pains, anemia, arthritis pains, asthma, blood pressure, bruises, burns, catarrh, colitis, constipation not due to intestinal obstruction, cuts, diabetes, eczema, enuresis (bed wetting), gastritis, goiters, hay fever, head colds, indigestion, insomnia due to nervousness, migraine headaches, neuralgia, neuritis, neurasthenia, nerve pains due to amputation, nervous stomach (neuroses of stomach), rheumatism, scalds, sciatica caused by poisons in the system, sinusitis, stomach gas, stomach ulcers, tonsillitis, toxemia, and varicose veins; and that water treated with the device would be efficacious in the cure, mitigation, and treatment of athlete's foot, dandruff, and falling hair; and that the device when used in conjunction with water treated with the device, would be efficacious in the treatment of shaking palsy.

DISPOSITION: A plea of not guilty having been entered, the case came up for trial before the court on December 29, 1949. The trial was concluded on December 31, 1949, and the defendant was found guilty. On June 6, 1950, the court imposed a fine of \$100.

DRUGS FOR VETERINARY USE

3159. Adulteration and misbranding of Eureka Poultry Mixture. U. S. v. 34 Packages, etc. (F. D. C. No. 29083. Sample No. 54430-K.)

LIBEL FILED: April 27, 1950, Southern District of Mississippi.

ALLEGED SHIPMENT: On or about February 16, 1950, by the Eureka Poultry Food Mfg. Co., from East St. Louis, Ill.

PRODUCT: 34 packages of *Eureka Poultry Mixture* at Smithdale, Miss., together with a number of circulars entitled "Don't Depend On Luck." Examination showed that the product contained less than the stated amounts of calcium, iron oxide, and phosphorus, and that it was short weight.

LABEL, IN PART: (Package) "Eureka Poultry Mixture * * * Not less than 74% Calcium, Not less than 10% Iron Oxide, Not less than .5% Phosphorus * * * Net Weight 1 Pound 12 Ounces."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess.

Misbranding, Section 502 (a), certain statements in the above-mentioned circulars were false and misleading since the article when used as directed was

not effective for the purposes represented. The statements represented and suggested that the article when used as directed was effective to save little chicks and to help protect them from gapes and worms; that the article when used as directed was effective as a treatment of cholera and roup of hens, as a chicken tonic, and as a remedy and medicine for chickens; that the article when used as directed was effective in the prevention and treatment of white diarrhea of chicks; and that the article when used as directed was effective to help hens lay more eggs in winter, to protect fowls from disease, and to keep them free from lice and mites. Further misbranding, Section 502 (b) (2), the article failed to bear a label containing an accurate statement of the quantity of the contents.

DISPOSITION: June 28, 1950. Default decree of condemnation and destruction.

3160. Misbranding of The Ball Solution. U. S. v. 25 Bottles * * *. F. D. C. No. 28728. Sample No. 1291-K.)

LIBEL FILED: February 20, 1950, Southern District of Florida.

ALLEGED SHIPMENT: On or about January 11, 1950, by the Timball Liniment Co., from Arcadia, Calif.

PRODUCT: 25 1-pint bottles of *The Ball Solution* at Hialeah, Fla.

LABEL, IN PART: "The Ball Solution * * * Veterinary * * * Contains: Alcohol 57.1%, Iodine, Potassium Iodide, Menthol, Eucalyptol, Methyl Salicylate, Oil of Peppermint."

NATURE OF CHARGE: Misbranding, Section 502 (a), the following label statements were false and misleading since the article was not effective in the prevention and treatment of the disease conditions of horses, stated and implied: "* * * Good for Bad Legs * * * apply two or three times a week in conditions such as: Buck Shins, Big Knee, Sprains, Swelling and Lameness * * * Osslets * * * Splints, Ringbone * * *."

DISPOSITION: June 8, 1950. Default decree of forfeiture and destruction.

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¹ (3157, 3158) Prosecution contested.

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¹ (3157, 3158) Prosecution contested.

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¹ (3157, 3158) Prosecution contested.

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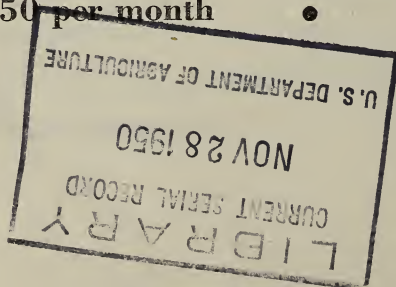
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<i>Aliens</i>	<i>Military Affairs</i>
<i>Atomic Energy</i>	<i>Money and Finance</i>
<i>Aviation</i>	<i>Patents</i>
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FEDERAL SECURITY AGENCY
FOOD AND DRUG ADMINISTRATION

**NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG,
AND COSMETIC ACT**

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3161-3180

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency. Published by direction of the Federal Security Administrator.

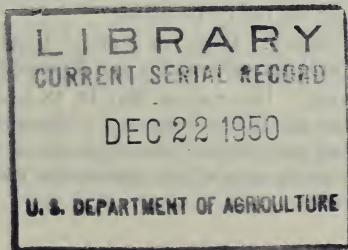
PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., November 17, 1950.

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*For presence of a habit-forming narcotic without warning statement, see Nos. 3162-3167; omission of, or unsatisfactory, ingredients statements, Nos. 3161-3163, 3165, 3168, 3169, 3177; failure to bear a label containing an accurate statement of the quantity of the contents, Nos. 3161-3169; failure to bear a label containing the name and place of business of the manufacturer, packer, or distributor, Nos. 3161-3169; cosmetic, actionable under the drug provisions of the Act, No. 3177.



DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE
DIRECTIONS OR WARNING STATEMENTS

3161. Misbranding of amphetamine hydrochloride tablets, dextro amphetamine hydrochloride tablets, and thyroid tablets. U. S. v. David Greenberg (Frank's Pharmacy). Plea of guilty. Fine, \$500. (F. D. C. No. 29118. Sample Nos. 51679-K, 51686-K, 51693-K, 52125-K, 52146-K.)

INFORMATION FILED: May 1, 1950, Southern District of Ohio, against David Greenberg, trading as Frank's Pharmacy, Cincinnati, Ohio.

INTERSTATE SHIPMENT: On or about January 24 and February 3, 1949, from the States of Illinois and Michigan into the State of Ohio.

ALLEGED VIOLATION: On or about June 12, July 24 and 30, and August 5, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused certain quantities of the drugs to be repacked and sold to various persons, which acts resulted in the repackaged drugs being misbranded.

LABEL, WHEN SHIPPED: "Amphetamine HCl 10 mgs. per tablet," "Dextro Amphetamine HCl 5 mgs. per tablet," and "Thyroid Strong * * * 50% Stronger than U. S. P."

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged drugs failed to bear labels containing the name and address of the manufacturer, packer, or distributor; Section 502 (b) (2), the *amphetamine hydrochloride tablets* and the *dextro amphetamine hydrochloride tablets* failed to bear labels containing a statement of the quantity of the contents; Section 502 (e) (1), the *amphetamine hydrochloride tablets* and the *dextro amphetamine hydrochloride tablets* failed to bear labels containing the common or usual name of the drugs; Section 502 (f) (1), the directions "Use as Directed," borne on the labeling of the *thyroid tablets*, were not adequate directions for use; and Section 502 (f) (2), the *amphetamine hydrochloride tablets* and the *dextro amphetamine hydrochloride tablets* failed to bear labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 12, 1950. A plea of guilty having been entered, the court imposed a fine of \$500.

3162. Misbranding of sulfathiazole tablets and Seconal Sodium capsules. U. S. v. Peoples Pharmacy, Inc., and Samuel I. Pigurski. Pleas of nolo contendere. Fine of \$150 plus costs, against defendants jointly. (F. D. C. No. 29114. Sample Nos. 60607-K to 60610-K, incl., 60613-K, 60614-K.)

INFORMATION FILED: April 25, 1950, Northern District of Indiana, against Peoples Pharmacy, Inc., Gary, Ind., and Samuel I. Pigurski, secretary-treasurer and pharmacist for the corporation.

INTERSTATE SHIPMENT: From the State of Illinois into the State of Indiana, of quantities of *sulfathiazole tablets* and *Seconal Sodium capsules*.

ALLEGED VIOLATION: On or about May 13, 18, and 23, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drugs to be repackaged and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents; and, Section 502 (e) (1), the repackaged *sulfathiazole tablets* failed to bear a label containing the common or usual name of the article.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which has been designated by regulations as habit forming; and when repackaged the capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged *Seconal Sodium capsules* bore no labeling containing directions for use; and Section 502 (f) (2), the *sulfathiazole tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 24, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$150, plus costs, against the defendants jointly.

3163. Misbranding of sulfadiazine tablets and Seconal Sodium capsules. U. S. v. Max Capestany, Jr. (Central Pharmacy), and David Hernandez. Pleas of nolo contendere. Fine of \$100 against defendant Capestany and \$50 against defendant Hernandez, plus costs. (F. D. C. No. 29113. Sample Nos. 60601-K, 60603-K, 60604-K.)

INFORMATION FILED: April 25, 1950, Northern District of Indiana, against Max Capestany, Jr., trading as the Central Pharmacy, Gary, Ind., and David Hernandez, a pharmacist in the pharmacy.

INTERSTATE SHIPMENT: From the State of Illinois into the State of Indiana, of quantities of *sulfadiazine tablets* and *Seconal Sodium capsules*.

ALLEGED VIOLATION: On or about May 13 and 23, 1949, while a number of the above-mentioned tablets and capsules were being held for sale at the Central Pharmacy after shipment in interstate commerce, various quantities of the tablets and capsules were repacked and sold without a prescription, which acts resulted in the repackaged tablets and capsules being misbranded.

Max Capestany, Jr., was charged with causing the acts of repacking and sale of the drugs involved in each of the three counts of the information; and, in addition, David Hernandez was charged in count 1 with causing such acts to be done in connection with the drug involved in that count.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which has been designated by regulations as habit forming; and when repackaged, the capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the article; Section 502 (f) (1), all lots of the repackaged drugs failed to bear

labeling containing adequate directions for use in that the directions "2 every 4 hours, 4 times a day," borne on the labeling of a portion of the *sulfadiazine tablets*, were not adequate directions for use, and since the other portion of the *sulfadiazine tablets* and the *Seconal Sodium capsules* bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 24, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$100 against defendant Capestany and a fine of \$50 against defendant Hernandez, together with costs.

3164. Misbranding of *sulfadiazine tablets*, *sulfadiazine lozenges*, and *Seconal Sodium capsules*. U. S. v. Claud A. Mecomber. Plea of nolo contendere. Defendant fined \$300, plus costs, and placed on probation for 3 years. (F. D. C. No. 28152. Sample Nos. 55442-K, 55444-K, 55446-K.)

INFORMATION FILED: April 25, 1950, District of Nebraska, against Claud A. Mecomber, manager of the drug department of Dryden's Drug Store, North Platte, Nebr.

INTERSTATE SHIPMENT: From the States of Missouri and Indiana into the State of Nebraska, of quantities of *sulfadiazine tablets*, *sulfadiazine lozenges*, and *Seconal Sodium capsules*.

ALLEGED VIOLATION: On or about June 13, 14, and 15, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused various quantities of the drugs to be repacked and sold without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged *Seconal Sodium capsules* bore no labels containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), the repackaged *Seconal Sodium capsules* and *sulfadiazine lozenges* bore no labels containing accurate statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been designated by regulations as habit forming; and the labels of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* and *sulfadiazine lozenges* bore no labeling containing accurate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 27, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$300, plus costs, against the defendant and placed him on probation for three years.

3165. Misbranding of *sulfadiazine tablets*, *Seconal Sodium capsules*, and *apiol and ergot compound capsules*. U. S. v. Walter R. Sarratt (North Side Drug Store). Plea of nolo contendere. Fine of \$300, plus costs, and

defendant placed on probation for 3 years. (F. D. C. No. 28133. Sample Nos. 55430-K, 55432-K, 55435-K.)

INFORMATION FILED: April 25, 1950, District of Nebraska, against Walter R. Sarratt, trading as the North Side Drug Store, North Platte, Nebr.

INTERSTATE SHIPMENT: From the State of Indiana into the State of Nebraska, of quantities of *sulfadiazine tablets*, *Seconal Sodium capsules*, and *apiol and ergot compound capsules*.

ALLEGED VIOLATION: On or about June 13, 14, and 15, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused a number of the tablets and capsules to be repackaged and sold without a prescription, which acts of the defendant resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been designated by regulations as habit forming; and the labels of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the article; and, Section 502 (e) (2), the repackaged *apiol and ergot compound capsules* failed to bear labels containing the common or usual name of each active ingredient, namely, *apiol*, oil of tansy, *ergot*, and *aloin*.

Further misbranding, Section 502 (f) (1), the repackaged *Seconal Sodium capsules* and *apiol and ergot compound capsules* bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* bore no labeling containing adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 27, 1950. A plea of *nolo contendere* having been entered, the court imposed a fine of \$300, plus costs, against the defendant and placed him on probation for 3 years.

3166. Misbranding of *pentobarbital sodium capsules*, *Dexedrine Sulfate tablets*, and *sulfonamides triplex tablets*. U. S. v. Harry W. Schaum Drug Co., Harry W. Schaum, and Howard H. W. Schulze. Plea of guilty for company and pleas of *nolo contendere* for individual defendants. Fine of \$1,000 against company; sentences against individual defendants suspended and these defendants placed on probation for 1 year. (F. D. C. No. 29121. Sample Nos. 60922-K, 60924-K, 60926-K, 60930-K to 60932-K, incl., 60959-K, 60975-K.)

INFORMATION FILED: May 23, 1950, Eastern District of Missouri, against the Harry W. Schaum Drug Co., a partnership, St. Louis, Mo., and Harry W. Schaum and Howard H. W. Schulze, partners and pharmacists.

INTERSTATE SHIPMENT: From the States of Illinois, Pennsylvania, and Indiana, into the State of Missouri, of quantities of *pentobarbital sodium capsules*, *Dexedrine Sulfate tablets*, and *sulfonamides triplex tablets*.

ALLEGED VIOLATION: On or about July 7, 21, and 25, and August 21 and 24, 1949, while a number of the above-mentioned capsules and tablets were being held for sale at the Harry W. Schaum Drug Co. after shipment in interstate commerce, various quantities of the capsules and tablets were repacked and sold without a prescription, which acts resulted in the repackaged tablets and capsules being misbranded.

The Harry W. Schaum Drug Co. was charged with causing the acts of repacking and sale of the drugs involved in each of the eight counts of the information; and, in addition, Harry W. Schaum, in four of the counts, and Howard H. W. Schulze, in the four other counts of the information, were charged with causing such acts to be done in connection with the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), a portion of the *sulfonamides triplex tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; and, Section 502 (b) (2), all of the repackaged drugs failed to bear labels containing statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *pentobarbital sodium capsules* contained a chemical derivative of barbituric acid, which derivative has been found to be, and by regulations designated as, habit forming; and the labels of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged drugs, with the exception of the *sulfonamides triplex tablets*, failed to bear labeling containing adequate directions for use since the directions for use "One at bedtime," borne on the labeling of the *pentobarbital sodium capsules*, were not adequate directions for use, and since the *Dexedrine Sulfate tablets* bore no labeling containing directions for use; and, Section 502 (f) (2), the labeling of the *sulfonamides triplex tablets* bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods of duration of administration.

DISPOSITION: June 12, 1950. A plea of guilty was entered on behalf of the company, and a plea of nolo contendere was entered on behalf of each individual defendant. The court, thereupon, imposed a fine of \$1,000 against the company, suspended the imposition of sentences against the individual defendants, and placed the individuals on probation for 1 year.

3167. Misbranding of sulfadiazine tablets, Seconal Sodium capsules, Dexedrine Sulfate tablets, and Ergoapiol with Savin capsules. U. S. v. Leroy M. Clayton (Jack Clayton Drug Store), and Paul E. Calmes. Pleas of guilty. File of \$200 against defendant Clayton and \$25 against defendant Calmes. (F. D. C. No. 29117. Sample Nos. 55801-K to 55808-K, incl.)

INFORMATION FILED: June 5, 1950, Western District of Oklahoma, against Leroy M. Clayton, trading as the Jack Clayton Drug Store, Clinton, Okla., and against Paul E. Calmes, pharmacist.

INTERSTATE SHIPMENT: From the States of Indiana, New York, and Pennsylvania, into the State of Oklahoma, of quantities of *sulfadiazine tablets*, *Seconal Sodium capsules*, *Ergoapiol with Savin capsules*, and *Dexedrine Sulfate tablets*.

NATURE OF CHARGE: While a number of the *Ergoapiol with Savin capsules* were being held for sale at the Jack Clayton Drug Store after shipment in interstate commerce, Leroy M. Clayton, on or about September 30, 1949, and Paul E. Calmes and Leroy M. Clayton, on or about October 3, 1949, caused the capsules to be sold and disposed of to two different purchasers in the original bottles in which the capsules had been shipped in interstate commerce, without requiring a prescription of a physician. When received by the defendant, the label of the capsules bore the statement "Caution—To be dispensed only by or on the prescription of a physician," and as a result the capsules were not required to comply with Section 502 (f) (1), which requires that adequate directions for use appear in the labeling. However, by selling the capsules without a prescription, the defendants caused the exemption to expire, resulting in the misbranding of the capsules, in violation of Section 502 (f) (1), since the bottles bore no labeling containing directions for use.

In addition to the above sales, defendant Clayton, on or about September 27 and 28 and October 3 and 4, 1949, caused various quantities of *sulfadiazine tablets*, *Seconal Sodium capsules*, and *Dexedrine Sulfate tablets* to be repackaged and sold without a prescription while they were being held for sale at the Jack Clayton Drug Store after shipment in interstate commerce, which acts resulted in the repackaged drugs being misbranded as follows: Sections 502 (b) (1) and (2), the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements setting forth the quantity of the contents.

Further misbranding, Section 502 (d), the repackaged *Seconal Sodium capsules* contained a derivative of barbituric acid, which derivative has been designated by regulations as habit forming; and when repackaged, the capsules bore no labeling containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the repackaged drugs bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* and *Dexedrine Sulfate tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 12, 1950. Pleas of guilty having been entered on behalf of the defendants, the court imposed a fine of \$200 against defendant Clayton and \$25 against defendant Calmes.

3168. Misbranding of *sulfadiazine tablets* and *apiol and ergotin compound capsules*. U. S. v. Stone's Pharmacy, Joseph H. Stone, and Leon Stone. Pleas of nolo contendere. Fine of \$200 against pharmacy and \$100 against each individual; in addition, pharmacy placed on probation for 2 years and each individual for 1 year. (F. D. C. No. 28135. Sample Nos. 55336-K, 55338-K.)

INFORMATION FILED: April 25, 1950, District of Nebraska, against Stone's Pharmacy, a partnership, North Platte, Nebr., and against Joseph H. Stone and Leon Stone, partners in the partnership.

INTERSTATE SHIPMENT: From the States of New York and Missouri into the State of Nebraska, of quantities of *sulfadiazine tablets* and *apiol and ergotin compound capsules*.

ALLEGED VIOLATION: On or about June 14 and 16, 1949, while a number of the above-mentioned tablets and capsules were being held for sale at Stone's Pharmacy after shipment in interstate commerce, various quantities of the tablets and capsules were repacked and sold without a prescription, which acts resulted in the repackaged tablets and capsules being misbranded.

Stone's Pharmacy was charged with causing the acts of repacking and sale of the drugs involved in each of the two counts of the information; and, in addition, Joseph H. Stone, in one of the counts, and Leon Stone, in the other count, were charged with causing such acts to be done in connection with the drugs involved in those counts.

NATURE OF CHARGE: Misbranding, Section 502 (b) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; Section 502 (b) (2), the repackaged *sulfadiazine tablets* and *apiol and ergotin compound capsules* failed to bear labels containing statements of the quantity of the contents; and, Section 502 (e) (1), the repackaged *sulfadiazine tablets* failed to bear a label containing the common or usual name of the drug.

Further misbranding, Section 502 (e) (2), the repackaged *apiol and ergotin compound capsules* failed to bear a label containing the common or usual name of each active ingredient since each capsule contained, in addition to apiol and ergotin, the active ingredient, aloin; and the label of the repackaged capsules failed to bear the common or usual name of the active ingredient, aloin.

Further misbranding, Section 502 (f) (1), the repackaged tablets and capsules bore no labeling containing directions for use; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 27, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$200 against the pharmacy and \$100 against each individual, plus costs, and placed the pharmacy on probation for a period of 2 years and each individual for a period of 1 year.

3169. Misbranding of apiol and ergot compound capsules. U. S. v. Davis Drug Co. and Wilford S. Nelson. Pleas of nolo contendere. Each defendant fined \$100, plus costs, and placed on probation for 1 year. (F. D. C. No. 28134. Sample No. 55457-K.)

INFORMATION FILED: April 25, 1950, District of Nebraska, against the Davis Drug Co., a partnership, North Platte, Nebr., and Wilford S. Nelson, a pharmacist for the partnership.

INTERSTATE SHIPMENT: On or about January 25, 1949, from the State of Indiana into the State of Nebraska.

ALLEGED VIOLATION: On or about June 16, 1949, while the capsules were being held for sale after shipment in interstate commerce, the defendants caused a number of the capsules to be removed from the bottle in which they had been shipped and to be repacked and sold without a prescription, which acts of the defendants resulted in the repackaged drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), the repackaged capsules failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents.

Further misbranding, Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients; the label of the repackaged capsules failed to bear the common and usual name of each active ingredient since the capsules contained, in addition to apiol and ergot, the active ingredients, oil of tansy and aloin; and the label of the repackaged capsules failed to bear the common and usual names of the last-named active ingredients.

Further misbranding, Section 502 (f) (1), the repackaged capsules bore no labeling containing directions for use.

DISPOSITION: June 27, 1950. Pleas of *nolo contendere* having been entered, each defendant was fined \$100, plus costs, and placed on probation for 1 year.

3170. Misbranding of Menestrex capsules. U. S. v. William Rex Manning (Rex Laboratories). Plea of guilty on counts 1, 2, 4, and 5; plea of not guilty on count 3. Count 3 tried to the court; verdict of not guilty. Fine of \$1.00 on each of counts 1, 2, 4, and 5. (F. D. C. No. 26719. Sample Nos. 260-K, 999-K, 27312-K, 44012-K.)

INFORMATION FILED: June 30, 1949, Middle District of Tennessee, against William Rex Manning, trading as the Rex Laboratories, Nashville, Tenn.

ALLEGED SHIPMENT: On or about August 28, 1947, and February 13, March 16, and September 8, 1948, from the State of Tennessee into the State of Georgia.

PRODUCT: Examination disclosed that the product contained a mixture of quinine sulfate and potassium permanganate.

LABEL, IN PART: (All bottle labels) "Menestrex Contains: Potassium Permanganate Quinine Sulphate"; (bottle label of lot covered by count 3) "For easing distress in scanty or functionally difficult menstruation."

NATURE OF CHARGE: Count 3. Misbranding, Section 502 (a), the label statement "Menestrex * * * For easing distress in scanty or functionally difficult menstruation" was false and misleading since the statement represented and suggested that the article would be efficacious to ease distress in scanty or functionally difficult menstruation, whereas the article would not be efficacious for such purpose.

Counts 1, 2, 4, and 5. Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the labeling failed to reveal the conditions for which the article was intended.

DISPOSITION: May 31, 1950. A plea of guilty was entered to counts 1, 2, 4, and 5, and a plea of not guilty to count 3. Trial was held before the court with respect to the charge involved in count 3, and, at its conclusion, a verdict of not guilty was rendered on count 3. The court imposed a fine of \$1.00 on each of counts 1, 2, 4, and 5, a total fine of \$4.00.

3171. Misbranding of estrogenic hormone substance. U. S. v. 20 Vials * * *. (F. D. C. No. 28964. Sample No. 55892-K.)

LABEL FILED: On or about April 19, 1950, Western District of Missouri.

ALLEGED SHIPMENT: On or about January 19, 1950, by the Robert Brinton Morris Laboratories, from Pitman, N. J.

PRODUCT: 20 vials, each containing 30 cc., of *estrogenic hormone substance* at Kansas City, Mo.

LABEL, IN PART: "Estrogenic Hormone Substance (As Estradiol In Sesame Oil)".

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use since the directions for use appearing therein "For Use in Menopausal Symptoms 5,000 units to 25,000 units Intramuscularly 2 or 3 Times Weekly" failed to disclose the amount of the drug to be injected.

DISPOSITION: May 25, 1950. Default decree of destruction.

3172. Misbranding of homeopathic tablets. U. S. v. 45 Cartons, etc. (F. D. C. No. 28476. Sample Nos. 49659-K to 49661-K, incl.)

LABEL FILED: December 21, 1949, District of Colorado.

ALLEGED SHIPMENT: On or about January 29, July 1, and October 17, 1949, by Ehrhart & Karl, from Chicago, Ill.

PRODUCT: 45 cartons of *homeopathic tablets*, 6 cartons of *Homeopathic Compound Tablets*, and 2 cartons of *Plain Bioplasma Celluids tablets* at Denver, Colo., in possession of the Colorado Mineral Health School.

Quantities of the tablets had been repackaged by, and were in possession of the Colorado Mineral Health School, together with a number of circulars, printed locally entitled "A Few Facts Worth Knowing," which accompanied the repackaged tablets.

LABEL, IN PART: (Cartons) "Tablet Triturates Homeopathic Private Formula No. * * * 1 Lb." and "Homeopathic Compound Tablets Private Formula No. 222a 6X * * * Added 50 Units Vitamin B₁ per tablet 1 Lb. * * *"; (packages) "A Biochemic Homeopathic Product Calcium Phosphate * * * No. 2 [or "Calcium Sulphate * * * No. 3," "Iron Phosphate * * * No. 4," "Potassium Chloride * * * No. 5," "Potassium Phosphate * * * No. 6," "Potassium Sulphate * * * No. 7," "Magnesium Phosphate * * * No. 8," "Sodium Phosphate * * * No. 9," "Sodium Phosphate * * * No. 10," "Sodium Sulphate * * * No. 11," "Silicea * * * No. 12"] Celluids," "A Biochemic Homeopathic Product Plain Bioplasma Celluids * * * A Combination of all the 12 minerals, prepared according to Bio-Chemistry Therapy * * * Each tablet contains 12 Minerals Potensised to the consistency of the blood according to Bio-Chemic Theory," and "A Biochemic Homeopathic Product Bioplasma Celluids * * * A Combination of all the 12 minerals, prepared according to Bio-Chemistry Therapy. * * * Each tablet contains not only the Mineral, but there has been added, 50 units of Vitamin B₁, to each tablet."

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the articles in the 45-carton, 6-carton, and 2-carton lots failed to bear adequate directions for use since they failed to bear any directions for use. The articles in such lots were misbranded in the above respect when introduced into and while in interstate commerce.

Misbranding, Section 502 (a), certain statements on the labels of the repackaged tablets and in the circulars accompanying such tablets were false and misleading since the articles were not capable of fulfilling the promises of benefit stated and implied by the statements. These statements represented and suggested:

That the *Celluids No. 2 tablets* would be beneficial for digestion, broken or weak bone structure, discharge of albumen, and after wasting illness; and that the tablets would be efficacious in the cure, mitigation, and treatment of Bright's disease, consumption, and catarrh;

That the *Cellaids No. 3 tablets* would be beneficial in the discharge of thick, yellow matter, which is sometimes mixed with blood; that the tablets would be effective to remove waste matter from the body through the liver route; and that they would be effective in the cure, mitigation, and treatment of boils, carbuncles, abscesses, pimples, and all pus conditions of the surface, not deep seated;

That the *Cellaids No. 4 tablets* would be beneficial in the treatment of feverish conditions, inflammation, burns, scalds, and cuts; and that the tablets would be effective in the treatment and prevention of congested conditions of any kind or place, such as inflammation, coughs, colds, chills, and pneumonia;

That the *Cellaids No. 5 tablets* would be beneficial in the treatment of the discharge of gray, thick phlegm, deep cough, swollen tonsils, and all soft swellings; that the tablets would be efficacious in the treatment and prevention of tonsillitis, scarlet fever, smallpox, measles, and chicken pox; that they were needed in the treatment of all burns, scalds, bruises, or any swollen conditions; and that they were needed by all growing children;

That the *Cellaids No. 6 tablets* would be beneficial in the treatment of nervous disorders, palpitation, difficult breathing, decay, and offensive discharges; that the tablets would build the gray nerve matter or the thinking part of the brain; that they would be effective in the treatment and prevention of deficient brain power, nervousness, lack of energy, paralysis, palpitation of the heart, sleeplessness, and insanity; and that they would be efficacious in the prevention of many cases of suicide;

That the *Cellaids No. 7 tablets* would be beneficial in the treatment of disturbed respiration and feverish conditions with dry skin; and that the tablets would open the pores of the skin and relieve the body of a hot, dry, and feverish condition;

That the *Cellaids No. 8 tablets* would be beneficial in the treatment of sharp, piercing pains; cramping, convulsions, and spasmodic conditions of any kind;

That the *Cellaids No. 9 tablets* would be beneficial in the treatment of simple colds, excessive flow of urine, watery eyes, sunstroke, and insect bites; and that the tablets would be effective in the cure, mitigation, and treatment of dropsy, hay fever, fresh colds, and sneezing;

That the *Cellaids No. 10 tablets* would be beneficial in the treatment of excess acid, sour stomach, nausea, discharge of creamy, yellow substance, and sour-smelling perspiration; that the tablets would prevent the thickening of bile and mucous; that they would be efficacious in the treatment and prevention of jaundice, colic, and bilious headache; and that they would be efficacious in the treatment of gout, acute and chronic rheumatism, and acid conditions;

That the *Cellaids No. 11 tablets* would be beneficial in the treatment of excess bile, chilly and feverish conditions, and yellow skin and eyeballs; and that the tablets were needed in the treatment of all diseases known as "colera," yellow fever, chills, fever and ague, flu, la grippe, and jaundice conditions;

That the *Cellaids No. 12 tablets* would be beneficial in the treatment of swellings of suppurative nature, discharge of thick, profuse pus, night sweats, and offensive feet; that the tablets would be efficacious in the removal of pus and waste accumulations from the body; that they would ripen boils, abscesses, and carbuncles, and would remove all traces of pus; and that they would be efficacious in the treatment of locomotor ataxia, constipation, asthma, and ulcers;

That the *Cellaids tablets Nos. 2 through 12* were necessary for the proper function of the body; and that the tablets alone, or in combination with proper food, would enable one to master any disease;

That the *Plain Bioplasma Cellaids tablets*, and the *Bioplasma Cellaids tablets containing vitamin B₁* would be beneficial as a general tonic.

DISPOSITION: March 17, 1950. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

3173. Adulteration of *Ru Nitrol tablets*. U. S. v. 1 Drum * * *. (F. D. C. No. 28987. Sample No. 72241-K.)

LABEL FILED: April 20, 1950, Northern District of Ohio.

ALLEGED SHIPMENT: On or about March 1, 1950, from Detroit, Mich. This was a return shipment.

PRODUCT: 1 unlabeled drum containing 18,000 *Ru Nitrol* tablets at Cleveland, Ohio.

LABEL, IN PART, WHEN ORIGINALLY SHIPPED: "Phenobarbital $\frac{1}{4}$ Gr. — Mannitol Hexanitate $\frac{1}{2}$ Gr., Rutin 20 Mg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported to possess. (Analysis showed that the article contained less than the stated amounts of phenobarbital, mannitol hexanitate, and rutin.)

DISPOSITION: July 28, 1950. Default decree of condemnation and destruction.

3174. Adulteration of *Semestrin*. U. S. v. 10 Packages * * *. (F. D. C. No. 28992. Sample No. 55890-K.)

LABEL FILED: On or about April 25, 1950, Western District of Missouri.

ALLEGED SHIPMENT: On or about August 12 and November 15, 1949, by the S. E. Massengill Co., from Bristol, Tenn.-Va.

PRODUCT: 10 packages, each containing 6 1-cc. ampuls, of *Semestrin* at Kansas City, Mo. Examination showed that the product contained, per 1 cc., materially less than 2 milligrams of highly purified estrogenic substance from the urine of pregnant mares, consisting mainly of estrone, with small amounts of other accompanying estrogens; and that the product possessed a potency, per 1 cc., materially less than 20,000 International Estrone Units.

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, 20,000 International Units of estrone (2 milligrams of estrogenic substance) per cubic centimeter.

DISPOSITION: June 22, 1950. Default decree of destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3175. Misbranding of *La Sierra Brand Formula M-G 5 (Male) tablets*. U. S. v. 3 Bottles, etc. (F. D. C. No. 29069. Sample No. 67655-K.)

LABEL FILED: April 21, 1950, District of Colorado.

*See also Nos. 3170. 3172.

ALLEGED SHIPMENT: On or about September 22, 1949, by James Audiss, Inc., from Los Angeles, Calif.

PRODUCT: 3 90-tablet bottles of *La Sierra Brand Formula M-G 5 (Male) tablets* at Denver, Colo., together with accompanying leaflets entitled "A Brief Explanation of the Endocrine (Glandular) System."

LABEL, IN PART: (Bottle) "La Sierra Brand * * * Formula M-G 5 (Male) A Natural Food Supplement Incorporated in a poly glandular base made from fresh inspected food animals, desiccated as follows: Prostate gland (of the ox) Suprarenal (Adrenal orchi substance (Testes)) Lecithin (Brain and spinal cord substance) Cortical-medullary Pineal Anterior pituitary Kidney Desiccated Brain Vitamin B₁ (Thiamin) 5 times the minimum adult requirement. Suggested dosage: As a dietary supplement three tablets daily or as directed by your doctor * * * This glandular substance * * * contains no known therapeutic value."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and in the accompanying leaflets were false and misleading since the article was not capable of fulfilling the promises of benefit stated and implied. The statements represented and suggested that the article was of particular benefit to males; and that because of its anterior pituitary, suprarenal, and testicular gland content, it was of benefit for promoting growth, increasing the growth of hair, reducing overweight individuals, stabilizing the normal blood pressure, controlling rheumatic ailments, providing a normal function of the male organs, and preventing premature senility, impotency or sex failure, prostate disturbance, and sterility.

DISPOSITION: June 1, 1950. Default decree of condemnation and destruction.

3176. Misbranding of Pan-Tone Medicine. U. S. v. 6 Cases, etc. (F. D. C. No. 29070. Sample No. 47665-K.)

LABEL FILED: April 19, 1950, Eastern District of Virginia.

ALLEGED SHIPMENT: During December 1949, and on or about March 6, 1950, by the Pan-Tone Drug Co., from Jacksonville, Fla.

PRODUCT: 6 cases, each containing 24 8-ounce bottles, of *Pan-Tone Medicine* at Emporia, Va., together with a number of circulars entitled "How Many Years Are You Going To Live?" Examination showed that the product consisted essentially of epsom salt, iron chloride, and water.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the circular were false and misleading. The statements represented and suggested that the article would promote longer life, purify the blood, and build up the body; and that the article was an adequate and effective treatment for rheumatism, neuralgia, neuritis, high blood pressure, lumbago, sciatica, constipation, nervousness, headaches, biliousness, kidney disorders, dizziness, backaches, swollen feet, and pains in the bones, joints, and muscles, loss of appetite, anemia, dyspepsia, indigestion, heartburn, bloating, boils, diabetes, hemorrhoids (bleeding piles), diarrhea, "that awful tired broken down feeling," and other troubles. The article was not capable of fulfilling the promises or benefits claimed, and was not an adequate and effective treatment for the disease conditions represented.

DISPOSITION: May 31, 1950. Default decree of condemnation and destruction.

3177. Misbranding of Chloresium Tooth Paste. U. S. v. 132 Cartons * * *. Motion filed by claimant to suppress Government's taking of deposition overruled and claim withdrawn. Decree of condemnation. (F. D. C. No. 27219. Sample No. 56325-K.)

LIBEL FILED: May 18, 1949, District of Connecticut; amended libel filed March 24, 1950.

ALLEGED SHIPMENT: On or about February 25, 1949, from Little Falls, N. J., by Mycoloid Laboratories, Inc., on behalf of Rystan Co., Inc., of Mount Vernon, N. Y.

PRODUCT: 132 cartons, each containing 1 tube, of *Chloresium Tooth Paste* and a circular bearing the same name at New Haven, Conn. Examination showed that the product was a green-colored tooth paste.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements in the labeling of the article were false and misleading since the article was not effective in the treatment of the conditions stated and implied: (Tube and carton) "Healing * * * aid in maintaining normal healthy gingival tissue * * * act as an adjunct to professional treatment of gum infections * * * stimulates healing; helps maintain healthy gums"; (display carton) "Healing"; and (circular in carton entitled "Chloresium Tooth Paste") "healing * * * improve and then maintain healthy gum tissue tone; help prevent gingival infections * * * healing * * * The natural cell-stimulating, antibiotic characteristics of these therapeutic chlorophyll derivatives make Chloresium Tooth Paste particularly valuable in cases of dental pathology * * * to maintain normal healthy gum tissue tone; accelerate healing; control superficial infection * * * will stimulate healing of gingival tissue, control superficial infection * * * Improve and help maintain healthy gum tissue tone * * * Assist in tightening of teeth loosened because of gum infections, by stimulating healthy, normal gum tissue growth * * * Contribute to the healing and repair of gingival tissue after extractions, ulcerations and contraction of the gums * * * Increase gum tissue resistance to infection * * * Supplement regular treatment by the dentist in helping to control and prevent recurrence of gum and mouth infections."

Further misbranding, Section 502 (e) (2), the product was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient, namely the bactericidal, abrasive, and detergent ingredients active "in the prophylactic maintenance of oral hygiene," as stated in the labeling of the product.

DISPOSITION: Rystan Co., Inc., appeared as claimant and filed an answer to the libel, denying that the product was misbranded. On March 22, 1950, the Government served notice upon counsel for the claimant for taking depositions pursuant to Rule 30 of the Federal Rules of Civil Procedure. A motion was filed on behalf of the claimant to suppress the Government's taking of depositions. A hearing in the matter was held before the court, and on March 27, 1950, the following ruling was made:

HINCKS, District Judge: "Contrary to my first impression, I have come to the conclusion that to facilitate its cross-examination of claimant's witnesses and to prepare its rebuttal to claimant's defense the government is entitled to the discovery through the proposed deponents which it names of all matters not privileged. At the hearing hereon, it seemed agreed that the proposed deponents will testify probably as experts for the claimant as to matters of opinion

based on research which they have done at claimant's instance in preparation for trial. Libellant insisted that the discovery was necessary not to elicit their opinions as experts but rather to ascertain the factual scope and nature of the research done so that it possibly may be in a better position to cross-examine these witnesses on trial and prepare a rebuttal to the claimant's defense. Having in mind that the field in question here is one of scientific controversy wherein without prior discovery cross-examination cannot be expected successfully to perform its historic function and effective evidence in rebuttal, though perhaps in existence, cannot be produced forthwith upon the close of the claimant's defense, I feel that here there is sufficient showing of necessity, within the rule of *Hickman v. Taylor* if applicable here, to allow the discovery to proceed.

"I hold also that this court is without power, especially in view of 28 U. S. C. 2412, to condition the government's right of discovery under the rules upon the payment of the claimant's attorneys' fees and expenses incurred in connection with the proposed depositions. If the government is not conditionally chargeable with costs (when its suit is unsuccessful), it seems scarcely consistent to rule that it may be unconditionally subjected to a substantial item irrespective of the outcome of its action."

Before the depositions were taken, the claimant advised that it desired to withdraw its claim. On June 13, 1950, the claimant filed a formal withdrawal of its claim, and on June 27, 1950, judgment of condemnation was entered. Thereupon, the court ordered that the product be delivered to a charitable institution.

3178. Misbranding of Farador device. U. S. v. 1 Device * * *. (F. D. C. No. 28723. Sample No. 61356-K.)

LIBEL FILED: February 16, 1950, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about August 6, 1949, by the E. S. Robbins Forwarding Co., from Englewood, Ohio.

PRODUCT: 1 *Farador device* at Moberly, Mo., together with 1 direction booklet. The device consisted of a metallic cylinder closed at both ends. To one end was attached, by means of wires, two metallic plates which were to be applied to various parts of the body while the cylinder was immersed in cold water.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the direction booklet were false and misleading. These statements represented and suggested that the device was adequate and effective for the prevention, treatment, and cure of most of the diseases of the human body, including, but not limited to, appendicitis, blood poison, tuberculosis, syphilis, spinal meningitis, apoplexy, convulsions, sexual debility, epilepsy, gonorrhea, infantile paralysis, malaria, paralysis, and heart disease. The device was not adequate or effective for the prevention, treatment, or cure of the diseases, conditions, and symptoms stated and implied.

DISPOSITION: May 22, 1950. Default decree of condemnation. The court ordered that the device and booklet be delivered to the Food and Drug Administration.

3179. Misbranding of steam cabinet device. U. S. v. 6 Devices, etc. (F. D. C. No. 28501. Sample No. 68350-K.)

LIBEL FILED: January 6, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about November 1, 1949, by the Healthmaster Steamette Co., from Burbank, Calif.

PRODUCT: 6 *steam cabinet devices* at Seattle, Wash., together with a number of accompanying leaflets. Examination showed that the device was a portable steam cabinet or Turkish bath. It consisted of plastic stretched over an alumi-

num frame with an opening at the front to permit entry, and was equipped with a seat and an electrically operated water boiler.

NATURE OF CHARGE: Misbranding, Section 502 (a), the following statements on the labeling of the article were false and misleading since the device was not effective in the treatment of the diseases, conditions, and symptoms stated and implied: (On leaflet entitled "Healthmaster Steamette") "Healthmaster * * * Circulation Reducing Nervousness Kidneys Liver Have a Cold? Arthritis Rheumatism * * * Complexion Elimination * * * speed in producing * * * circulation"; (on leaflet entitled "Means Easier Profits for You") "Healthmaster * * * Induces stimulation of circulatory system and excretion of waste materials through skin. * * * as a general body conditioning and health aid"; and (on leaflet entitled "Facts About The Healthmaster Steamette") "Healthmaster * * * improving his health through the use of steam * * * For persons who are overweight a steam bath is very beneficial in reducing. Healthful in eliminating toxic poison from your system through the pores. Colds are many times broken more easily after excessive perspiration. Persons who suffer from insomnia are greatly benefited by a steam bath before retiring. Will aid in cases of over-indulgence. If you are tired and nervous a treatment in the cabinet will relax and rest you. Cases of arthritis, rheumatism, or muscular fatigue are many times greatly improved by the relaxing action of a steam bath."

DISPOSITION: June 21, 1950. The case having been removed to the Northern District of California for final disposition and the Healthmaster Steamette Co., claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling, under the supervision of the Federal Security Agency.

DRUG FOR VETERINARY USE

3180. Misbranding of Sulfa-Tome. U. S. v. 1½ Drums * * *. (F. D. C. No. 29320. Sample No. 81105-K.)

LABEL FILED: May 15, 1950, District of Delaware.

ALLEGED SHIPMENT: On or about April 27, 1950, by C. J. Lurenz, from Salisbury, Md.

PRODUCT: 1½ drums (approximately 150 pounds) of *Sulfa-Tome* at Frankford, Del. Analysis showed that the product contained no sulfathiazole sodium or any other sulfonamide drug.

LABEL, IN PART: "Sulfa-Tome Soluble Veterinary."

NATURE OF CHARGE: Misbranding, Section 502 (a), the name of the drug and the following label statements were false and misleading: "Sulfa-Tome Soluble * * * (Brand of Sulfathiazole Sodium) * * * For Infectious Coryza In Poultry:—When symptoms of common Colds or Coryza occur in the Flock, add this powder to all the drinking water for 3 to 5 days. When the majority of the birds are free from symptoms use the Powder for one more day. * * * Dosage for Coryza in Poultry * * * Amount of Sulfa-Tome * * * Warning—Dosage to excess with Sodium Sulfathiazole will cause Toxic reactions." The article contained no form of any sulfonamide drug, as the name of the drug and other label reference to sulfathiazole represented and suggested, and the article was not effective in the prevention and treatment of common colds or coryza of poultry.

DISPOSITION: June 6, 1950. Default decree of condemnation and destruction.

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¹ (3177) Seizure contested. Contains ruling of the court.

² (3170) Prosecution contested.



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FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

3181-3200

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by the United States attorneys, acting upon reports submitted by the Federal Security Agency, and include, where indicated, the results of investigations of the Agency, prior to the institution of the proceedings. Published by direction of the Federal Security Administrator.

PAUL B. DUNBAR, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., September 30, 1950

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DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS

3181. Misbranding of methyl testosterone tablets. U. S. v. Louis Needman (West Coast Prescription Pharmacy). Plea of nolo contendere. Fine, \$50. (F. D. C. No. 28204. Sample Nos. 31524-K, 31527-K.)

INFORMATION FILED: March 27, 1950, Southern District of California, against Louis Needman, trading as the West Coast Prescription Pharmacy, Los Angeles, Calif.

INTERSTATE SHIPMENT: Between the approximate dates of December 22, 1948, and June 15, 1949, from the State of New Jersey into the State of California.

ALLEGED VIOLATION: On August 4 and 8, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendant removed a number of *methyl testosterone tablets* from the bottle in which they had been shipped in interstate commerce and repacked them in a small bottle and sold them without a prescription; also, on August 8, the defendant sold a number of *methyl testosterone tablets* in the bottle in which they had been shipped in interstate commerce, after first relabeling the bottle, and sold them without a physician's prescription, which acts of the defendant resulted in the repackaged and relabeled tablets of drug being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, in that each tablet contained 10 milligrams of methyl testosterone and the use of a drug containing 10 milligrams of methyl testosterone in each tablet with the frequency prescribed, recommended, and suggested in the labeling, namely, as directed on the labels, "1-2 linguets daily" and "1-2 daily," would be dangerous to health since such use of the article may result in sterility and would stimulate the growth of carcinoma of the prostate gland; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in that there was no statement in the labeling of any condition, disease, or function for which the article was to be used.

DISPOSITION: May 22, 1950. A plea of nolo contendere having been entered, the court imposed a fine of \$50.

3182. Misbranding of Gattis worm oil. U. S. v. 120 Bottles * * *. (F. D. C. No. 29216. Sample No. 72940-K.)

LABEL FILED: May 23, 1950, Western District of Kentucky.

ALLEGED SHIPMENT: On or about April 19, 1950, by the Gattis Chemical Co., from Nashville, Tenn.

PRODUCT: 120 1-ounce bottles of *Gattis worm oil* at Owensboro, Ky. Examination disclosed that the product had the composition stated on its label.

LABEL, IN PART: "Gattis Worm Oil Each Fluid Ounce Contains: 22 Mins. Oil Worm Seed 12 Mins. Chloroform 421 Mins. Castor Oil, Turpentine, Combined With Aromatics. Directions: Children 2 to 5 Years Old, One-Half Teaspoonful; 5 to 10 Years Old, One Teaspoonful; Adults, One And A Half Teaspoonfuls. One Dose Morning And Night (May Be Given For 2 Or 3 Days If Necessary)."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling.

DISPOSITION: July 3, 1950. Default decree of condemnation and destruction.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

3183. Misbranding of Stops (antihistamine tablets). U. S. v. 24 Display Cards, etc. (F. D. C. No. 29249. Sample No. 67424-K.)

LABEL FILED: June 7, 1950, Southern District of West Virginia.

ALLEGED SHIPMENT: On or about March 27, 1950, by the Research Associates, from Decatur, Ill.

PRODUCT: 24 display cards, each containing 26 packages, of *Stops* at Bluefield, W. Va., together with a number of window streamers entitled "Stops." Analysis showed that the product contained pyranisamine maleate.

LABEL, IN PART: (Package) "Stops 12 Anti-Histamine Tablets Each Tablet Contains 25 MG. Anisopyramine."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statements "Stops Colds, Stops Coughs" appearing in the labeling of the article, namely, on the package label, display card, and window streamer, were false and misleading since the article was not an adequate and effective treatment for those conditions; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient since pyranisamine maleate was not declared.

The article also was in violation of Section 505 (a), since it was a new drug within the meaning of the law, and an application filed pursuant to the law was not effective with respect to the article.

DISPOSITION: June 28, 1950. Default decree of condemnation and destruction.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

3184. Misbranding of pentobarbital sodium capsules. U. S. v. C. Thomas Newell. Plea of nolo contendere. Fine, \$100. (F. D. C. No. 28122. Sample Nos. 1852-K, 1858-K, 1860-K, 1864-K.)

INFORMATION FILED: April 1, 1950, Southern District of Florida, against C. Thomas Newell, pharmacist for the Everglades Pharmacy, Palm Beach, Fla.

INTERSTATE SHIPMENT: From the State of Illinois into the State of Florida, of quantities of *pentobarbital sodium capsules*.

ALLEGED VIOLATION: On or about June 3, 10, 24, and 29, 1949, while the drug was being held for sale at the Everglades Pharmacy after shipment in interstate commerce, C. Thomas Newell caused various quantities of the *pentobarbital sodium capsules* to be repacked and sold without a physician's prescription, which acts resulted in the capsules being misbranded.

NATURE OF CHARGE: Misbranding, Section 502 (b) (2), the repackaged capsules bore no label containing a statement of the quantity of the contents.

Further misbranding, Section 502 (d), the capsules contained a chemical derivative of barbituric acid, which derivative has been found to be, and by

* See also No. 3181.

regulations designated as, habit forming; and the label of the repackaged capsules failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (f) (1), the labeling of the repackaged capsules failed to bear adequate directions for use since the directions for use "One capsule to induce sleep as directed," borne on the labeling, were not adequate directions for use.

DISPOSITION: July 28, 1950. A plea of *nolo contendere* having been entered, the court imposed a fine of \$100.

3185. Misbranding of sulfadiazine tablets, Seconal Sodium capsules, and thyroid tablets. U. S. v. Frank Albright (Albright Drug Store). Plea of *nolo contendere*. Fine of \$150, plus costs. (F. D. C. No. 29416. Sample Nos. 61661-K, 61662-K, 61736-K.)

INFORMATION FILED: July 7, 1950, Western District of Kentucky, against Frank Albright, trading as the Albright Drug Store, Paducah, Ky.

INTERSTATE SHIPMENT: From the State of Indiana into the State of Kentucky, of quantities of *sulfadiazine tablets*, *Seconal Sodium capsules*, and *thyroid tablets*.

ALLEGED VIOLATION: On or about September 17 and 27, 1949, while the drugs were being held for sale after shipment in interstate commerce, the defendant caused certain quantities of the drugs to be repacked and sold without a prescription, which acts resulted in the drugs being misbranded.

NATURE OF CHARGE: Misbranding, Sections 502 (b) (1) and (2), all of the repackaged drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and statements of the quantity of the contents.

Further misbranding, Section 502 (d), the *Seconal Sodium capsules* contained a chemical derivative of barbituric acid, which has been designated as habit forming; and when repackaged, the capsules bore no label containing the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

Further misbranding, Section 502 (e) (1), the repackaged *sulfadiazine tablets* and *thyroid tablets* failed to bear labels containing the common or usual name of the drugs; Section 502 (f) (1), the labeling of all of the repackaged drugs failed to bear directions for use; and, Section 502 (f) (2), the repackaged *sulfadiazine tablets* bore no labeling containing warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: July 20, 1950. A plea of *nolo contendere* having been entered, the court imposed a fine of \$150, plus costs.

3186. Misbranding of sulfathiazole tablets. U. S. v. Bowers' Pharmacy and Cloyce A. Bowers. Pleas of *nolo contendere*. Fine of \$100, plus costs, against defendants jointly. (F. D. C. No. 29112. Sample Nos. 15894-K, 15896-K, 60615-K.)

INFORMATION FILED: April 28, 1950, Northern District of Indiana, against the Bowers' Pharmacy, a partnership, Gary, Ind., and against Cloyce A. Bowers, a partner in the partnership.

INTERSTATE SHIPMENT: From the State of Illinois into the State of Indiana, of a quantity of *sulfathiazole tablets*.

ALLEGED VIOLATION: On or about May 13, 18, and 23, 1949, while the drug was being held for sale after shipment in interstate commerce, the defendants caused various quantities of the drug to be repackaged and sold without a physician's prescription, which acts of the defendants resulted in the drug being misbranded.

NATURE OF CHARGE: Misbranding. Sections 502 (b) (1) and (2), the repackaged tablets failed to bear the name and place of business of the manufacturer, packer, or distributor, and a statement of the quantity of the contents; Section 502 (e) (1), a portion of the repackaged tablets failed to bear a label containing the common or usual name of the drug; Section 502 (f) (1), the labeling of the repackaged tablets bore no directions for use; and, Section 502 (f) (2), the labeling of the repackaged tablets bore no warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration.

DISPOSITION: June 24, 1950. Pleas of *nolo contendere* having been entered, the court imposed a fine of \$100, plus costs, against the defendants jointly.

3187. Misbranding of Private Formula tablets and Pruvo tablets. U. S. v. 3 Drums, etc. (F. D. C. No. 28008. Sample Nos. 60449-K, 60450-K.)

LIBEL FILED: September 29, 1949, Eastern District of Wisconsin.

ALLEGED SHIPMENT: On or about September 22, 1949, by the Standard Pharmaceutical Co., from Chicago, Ill.

PRODUCT: 3 drums containing 209,000 *Private Formula tablets*, together with 28 cases, each containing 6 dozen bottles of 75 tablets each, of *Pruvo tablets* at Milwaukee, Wis., in possession of the Pruvo Pharmaceutical Co. The bottles of *Pruvo tablets*, with each of which was enclosed a circular entitled "Pruvo," had been repacked from 3 drums of *Private Formula tablets* included in the above-mentioned shipment. The bottles were labeled by the consignee, but no written agreement existed between the shipper and the consignee as to labeling such as is contemplated under Section 503 (a) of the Act and the regulations thereunder.

LABEL, IN PART: (Drums) "Private Formula No. P-25,897 Prepared for Wm. SLK Laboratories * * * Each tablet represents: Calcium Succinate 3 gr. Aspirin 4 gr. Caution—to be dispensed only by or on the prescription of a physician * * * This is a bulk shipment intended for repackaging" and (bottle) "Pruvo Acetylsalicylic Acid 4 grains Calcium Succinate 3 grains * * * for Arthritic, Neuritic, Rheumatic Pain Relief."

NATURE OF CHARGE: Misbranding (tablets in drums), Section 502 (f) (1), the labeling of the tablets failed to bear adequate directions for use. The tablets were misbranded when introduced into and while in interstate commerce.

Misbranding (tablets repacked into bottles), Section 502 (a), certain statements on the bottle label and in the circular were false and misleading. The statements represented and suggested that the article was adequate and effective for the treatment and cure of rheumatism and arthritis, whereas the article was not adequate and effective for the treatment and cure of rheumatism and arthritis; and, Section 502 (e) (2), the label of the article

failed to bear the common or usual name of each of its active ingredients since acetylsalicylic acid is not the common or usual name of aspirin. The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: November 21, 1949, and July 14, 1950. The Standard Pharmacal Co., claimant for the 3 drums of the *Private Formula tablets*, and the Pruvo Pharmacal Co., claimant for the 28 cases of *Pruvo tablets*, having consented to the entry of decrees, judgments of condemnation were entered and the court ordered that the tablets be released under bond for relabeling, under the supervision of the Food and Drug Administration.

3188. Misbranding of Fluid Extract No. 118 Celery Fruit (celery seed) and Green's Celery Compound. U. S. v. 10 Bottles, etc. (F. D. C. No. 28463. Sample Nos. 43310-K to 43312-K, incl.)

LABEL FILED: January 5, 1950, Northern District of Illinois.

ALLEGED SHIPMENT: On or about May 27, July 28, and October 20, 1949, by Eli Lilly & Co., from Indianapolis, Ind.

PRODUCT: 10 1-gallon bottles of *Fluid Extract No. 118 Celery Fruit (celery seed)*, and 10 1-gallon bottles, 106 15-cc. bottles, and 49 30-cc. bottles of *Green's Celery Compound*, at Chicago, Ill., in possession of Green Laboratories (Green Drug Co.), together with various promotional literature.

RESULTS OF INVESTIGATION: The product had been shipped in interstate commerce in gallon bottles under the label "Fluid Extract No. 118 Celery Fruit (celery seed)." A number of the gallon bottles had been relabeled, and some of the product in other gallon bottles had been repacked and relabeled as "Green's Celery Compound" by the consignee, Green Laboratories (Green Drug Co.). The promotional literature, which had been prepared by the consignee, consisted of 10,000 copies each of cards entitled "Attention Users of Green's Celery Compound" and "Why Suffer from Arthritis?" and a leaflet entitled "The Story of Green's Celery Compound," including copies packaged with the 15-cc. and 30-cc. size bottles, and 2,500 posters entitled "Why Suffer From Arthritis?"

LABEL, IN PART: (10 1-gallon bottles labeled when shipped) "Fluid Extract No. 118 Celery Fruit (celery seed) (*Apium graveolens*) Contains Alcohol 79 percent"; (10 1-gallon bottles and 15-cc. and 30-cc. bottles labeled after receipt in interstate commerce) "Green's Celery Compound Improved * * * Active Ingredient: *Apium Fructus*, Alcohol 72%."

NATURE OF CHARGE: *Fluid Extract No. 118 Celery Fruit (celery seed)*. Misbranding, Section 502 (f) (1), the labeling failed to bear adequate directions for use since it failed to state the purposes for which the article was to be used and the frequency and duration of administration. The article was misbranded in the above respect when introduced into and while in interstate commerce.

Green's Celery Compound. Misbranding, Section 502 (a), certain statements in the labeling were false and misleading since they represented and suggested that the article was adequate and effective in the treatment of arthritis, rheumatism, lumbago, neuritis, and sciatica, whereas the article was not adequate and effective in the treatment of such conditions. The relabeled article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: July 12, 1950. Default decree of condemnation and destruction.

3189. Misbranding of Green Dragon liniment. U. S. v. 144 Bottles, etc. (F. D. C. No. 27877. Sample No. 48351-K.)

LIBEL FILED: September 26, 1949, Middle District of Pennsylvania; amended libel filed, February 1, 1950.

ALLEGED SHIPMENT: On or about September 10, 15, 19, and 20, 1949, from Cincinnati, Ohio, by the Green Dragon Medicine Co.

PRODUCT: 144 2-ounce bottles, and 6 cases, each containing 72 2-ounce bottles, of *Green Dragon liniment* at Lebanon, Pa. The libel was amended to cover goods actually seized, i. e., 48 bottles, and 20 cases, each containing 72 bottles.

RESULTS OF INVESTIGATION: This product was represented by Al Stofel, salesman for the distributor, the Green Dragon Medicine Co., during lectures delivered by him at the Allentown Fairgrounds on September 21, 1949, to be effective for stomach pains, rheumatic pains, arthritic pains, catarrh, and hay fever, and as a cure for any human pain in one to three minutes.

NATURE OF CHARGE: Misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended.

DISPOSITION: June 12, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS*

3190. Action to enjoin and restrain the interstate shipment of Acidofilac. U. S. v. Helen A. Walters (Radiance Products Co.). Consent decree granting injunction. (Inj. No. 220.)

COMPLAINT FILED: Between December 1, 1949, and January 26, 1950, Southern District of California, against Helen A. Walters, an individual, and as administratrix of the estate of William R. Walters, doing business under the name, Radiance Products Co., Los Angeles, California.

NATURE OF CHARGE: The defendant had been and was at the time of filing the complaint introducing and delivering for introduction into interstate commerce at Los Angeles, Calif., consignments of a drug designated as "Acidofilac," which was a culture of lactic acid-forming organisms and which was adulterated and misbranded in the following respects:

Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess since it was represented to possess a count of seven billion eight-hundred million viable *acidophilus* bacteria in each fluid ounce, whereas the article contained substantially less viable *acidophilus* bacteria in each fluid ounce.

Misbranding, Section 502 (a), the statements in the accompanying leaflet entitled "Acidofilac A vitalized pure aciduric bacterial milk food" represented and suggested that the use of the article would result in the prolongation of life; in outwitting middle age; and in keeping the system free from putrefactive bacteria and toxic poisons, resulting in the prolongation of the vigorous period of life; and that the article was useful in the treatment of certain stomach disorders, which statements were false and misleading since the article was not capable of fulfilling such promises of benefit. In addition,

* See also No. 3200.

the statement "A recent test made by the Truesdail Laboratories, Inc., of August 31, 1943, shows a count of seven billion eight hundred million viable acidophilus bacteria in each fluid ounce of bottle tested," contained in the accompanying leaflet, was misleading since the article contained only a small proportion of the number of viable *acidophilus* bacteria represented by such statement; and, the statement "Acidofilac A vitalized aciduric bacterial food A composite culture of selected strains of *Lactobacilli-Acidophilus* and *Bulgaricus* in skim milk. It is best to use before Oct. 11, 1949," appearing on the label of the article, was misleading since the statement represented and suggested that in the recommended dose stated on the label the article would supply prior to the date stated a therapeutically significant number of viable *Lactobacilli acidophilus* and *bulgaricus*, whereas it would not do so.

The complaint alleged further that unless restrained, the defendant would continue to introduce and deliver for introduction into interstate commerce the adulterated and misbranded article.

PRAYER OF COMPLAINT: That the defendant be perpetually enjoined from commission of the acts complained of.

DISPOSITION: August 1, 1950. The defendant having consented to the entry of a decree, the court issued an order permanently enjoining the defendant from shipping in interstate commerce any *Acidofilac* or any like drug which was adulterated and misbranded as alleged in the complaint.

3191. Adulteration of Creme-A-Tone and adulteration and misbranding of Vextrin capsules, Trestilon tablets, Elgyn capsules, Folitrin tabsules, Slix tablets, and Estra-Beta capsules. U. S. v. Oxford Products, Inc. Plea of guilty. Fine of \$1,300, plus costs. (F. D. C. No. 28112. Sample Nos. 353-K, 354-K, 358-K, 2252-K to 2254-K, incl., 3130-K, 21365-K, 21366-K, 30739-K, 30740-K, 42129-K, 43432-K, 43433-K.)

INFORMATION FILED: June 14, 1950, Northern District of Ohio, against Oxford Products, Inc., Cleveland, Ohio.

ALLEGED SHIPMENT: Between the approximate dates of March 15, 1948, and March 14, 1949, from the State of Ohio into the States of Georgia, West Virginia, Virginia, Missouri, California, Illinois, and Michigan.

NATURE OF CHARGE: *Creme-A-Tone*. Adulteration, Section 501 (b), the article purported to be and was represented as aluminum hydroxide gel, a drug the name of which is recognized in the United States Pharmacopoeia, an official compendium, and its strength differed from the official standard; and the difference in the strength of the article from the standard was not plainly stated, or stated at all, on its label. The standard provides that aluminum hydroxide gel contains the equivalent of not less than 3.6 percent of aluminum oxide, and that the volume of tenth-normal acid required to neutralize one gram of aluminum hydroxide gel shall be not less than 12.50 cc. All shipments of the article contained the equivalent of less than 3.6 percent of aluminum oxide, and in one of the shipments the volume of tenth-normal acid required to neutralize one gram of the article was less than 12.50 cc.

Vextrin capsules, Trestilon tablets, Elgyn capsules, Folitrin tabsules, Slix tablets, and Estra-Beta capsules. Adulteration, Section 501 (c), the strength of the articles differed from that which they purported and were represented to possess. Misbranding, Section 502 (a), certain statements in the labeling

of these products relating to their declared strength were false and misleading. The statements represented and suggested:

That each *Vextrin capsule* contained 20 milligrams of iron and would supply 2 times the minimum adult daily requirement for iron;

That 4 *Trestilon tablets* would furnish 2,000 percent of the daily minimum requirement of iron for adults and 50 percent of the daily minimum requirement of calcium for adults;

That each *Elgyn capsule* contained 20 milligrams of iron and would supply 2 times the minimum adult daily requirement for iron;

That two *Folitrin tabsules* would provide the minimum adult daily requirement for iron;

That 9 of the *Sliz tablets* contained 460 milligrams of calcium and 360 milligrams of phosphorus, and that 9 such tablets contained 50 percent of the minimum daily requirements for calcium and phosphorus;

That each *Estra-Beta capsule* contained 30 milligrams of niacinamide and 20 milligrams of iron and would supply 2 times the minimum adult daily requirement for iron.

The *Vextrin capsules*, *Trestilon tablets*, *Elgyn capsules*, *Folitrin tabsules*, and *Sliz tablets* were deficient in the above named ingredients; and one shipment of the *Estra-Beta capsules* contained less than 30 milligrams of niacinamide, and the other shipment contained less than 20 milligrams of iron and would supply less than 2 times the minimum adult daily requirement for iron.

DISPOSITION: June 14, 1950. A plea of guilty having been entered, the court imposed a fine of \$1,300, plus costs.

3192. Adulteration and misbranding of prophylactics. U. S. v. 50 Gross * * *.
(F. D. C. No. 28891. Sample No. 68860-K.)

LIBEL FILED: March 24, 1950, Western District of Washington.

ALLEGED SHIPMENT: On or about January 11 and February 10, 1950, by the Dean Rubber Mfg. Co., from Kansas City, Mo.

PRODUCT: 50 gross of *prophylactics* at Seattle, Wash. Examination of samples showed that 2.3 percent were defective in that they contained holes.

LABEL, IN PART: "Dean's Peacocks Reservoir Ends."

NATURE OF CHARGE: Adulteration, Section 501 (c), the quality of the article fell below that which it purported and was represented to possess.

Misbranding, Section 502 (a), the label statement "Tested On New, Modern Equipment For Your Protection * * * An Aid In Preventing Venereal Diseases" was false and misleading as applied to articles containing holes.

DISPOSITION: September 11, 1950. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS

DRUGS FOR HUMAN USE*

3193. Misbranding of Amberin. U. S. v. Bernard A. Brownlow (The Amberin Co.). Plea of not guilty. Tried to the court. Verdict of guilty. Sentence of 10 months in a Federal work camp. (F. D. C. No. 26737. Sample Nos 41032-K, 41036-K.)

* See also Nos. 3183, 3187, 3188, 3190-3192.

INFORMATION FILED: October 19, 1949, Eastern District of Washington, against Bernard A. Brownlow, trading as the Amberin Co., Walla Walla, Wash.

ALLEGED SHIPMENT: On or about December 23, 1948, and February 7, 1949, from the State of Washington into the State of Montana.

LABEL, IN PART: "Amberin * * * For Hemorrhoids Active Ingredients Worm Wood Menthol Acetone Thymol \$10 Manufactured for Amberin Company Walla Walla, Washington."

NATURE OF CHARGE: Misbranding, Section 502 (a), the label statement "For Hemorrhoids" was false and misleading since the article would not be efficacious in the cure, mitigation, and treatment of hemorrhoids.

DISPOSITION: July 21, 1950. A plea of not guilty having been entered, the case came on for trial before the court without a jury. At the conclusion of the trial, the court found the defendant guilty and sentenced him to serve 10 months in a Federal work camp.

3194. Misbranding of ViViBx tablets and ViViBx capsules. U. S. v. International Pharmaceutical Co. and Frederick Herrschner. Pleas of nolo contendere. Fine of \$1,000, plus costs, against defendants jointly. (F. D. C. No. 26698. Sample Nos. 7097-K, 16842-K, 31615-K to 31617-K, incl.)

INFORMATION FILED: May 26, 1949, Northern District of Illinois, against the International Pharmaceutical Co., a corporation, trading as Frederick Herrschner, Chicago, Ill., and against Frederick Herrschner, president of the corporation.

ALLEGED SHIPMENT: On or about March 22 and 31 and April 7 and 13, 1948, from the State of Illinois into the States of New York, Wisconsin, and California.

LABEL, IN PART: "ViViBx * * * Vitamin D and A Tablets Fortified with Vitamin E. Each tablet contains: Vitamin D 25,000 U. S. P. Units Vitamin A 5,000 U. S. P. Units Vitamin E 5,000 Micrograms and supplies 62.5 times MDR Vitamin D and 100% Vitamin A. Need not yet determined for Vitamin E (tocopherols)"; "ViViBx Whole Natural B Complex Tablets (From Special Selected Strain of Highest Potency Yeast) Each Tablet Contains: Vitamin B₁ 1220 Micrograms Vitamin B₂ 2400 Micrograms Niacin 160 Micrograms Pantothenic Acid 88 Micrograms Plus all other factors of the B Complex Natural to Yeast, including 18 Amino Acids, 11 minerals"; "ViViBx * * * Vitamin E Concentrate Capsules * * * Each capsule contains 39.4 mg. of mixed natural Tocopherols. Equivalent to 30 mg. of Alpha-Tocopherol in biological activity"; "ViViBx * * * Super Capsules Vitamins in each capsule A 5,000 U. S. P. units B₁ 666 U. S. P. units D 800 U. S. P. units B₆ 50 Gamma G (B₂) 2,000 Gamma C 600 U. S. P. units K 10 Gamma Niacin Amide 10,500 Gamma Calcium Pantothenate 1,000 Gamma Wheat Germ Oil 171,000 Gamma"; and "ViViBx * * * High Potency Vitamin C (Ascorbic Acid) Each tablet contains 100 Milligrams (2000 U. S. P. or Intn'l Units) of Vitamin C—furnishing 3½ times or 333% of the adult minimum daily requirement."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in circulars entitled "Price List of ViViBx," accompanying all of the articles, "Save Safely 20% Sale," accompanying all of the articles except for the B complex tablets, and "Aglow With Life," accompanying the vitamin E capsules, were false and misleading since the articles would not be efficacious for the purposes represented and suggested. The statements represented and suggested:

That the *ViViBx vitamins D and A tablets* would be efficacious to nourish the bones, nerves, and internal membranes, and would be adequate and effective for the treatment of arthritis, rheumatism, swollen joints, and muscular atrophy;

That the *ViViBx whole natural B complex tablets* would be efficacious in the treatment of diabetic conditions, simple anemia, bad breath, dental caries, glossitis, acne, and other minor skin afflictions;

That the *ViViBx vitamin E concentrate capsules* would be efficacious to protect the body's vitamin A reserves, and to prevent fatty livers; that it would be efficacious in the treatment and prevention of muscular ailments, and diseases of the human heart; that it would protect the body's vitamins, hormones, and fats, and would nourish the muscles, including those of the heart; that it would prevent loss of, or serious damage to, the membranes of the sex organs; that it would be efficacious to prevent gastric ulcers; that it would ease rheumatic pain; that it would be helpful during the menopause; that it would be efficacious to prevent abortion and would be of value in pregnancies; that it would be efficacious in the prevention and treatment of hot flashes; and that it would be of value in the formation and preservation of tooth enamel;

That the *ViViBx Super capsules* would be efficacious to prevent food rancidity in the body and to build body resistance against colds, fatigue, nervousness, irritability, and tooth decay;

That the *ViViBx high potency vitamin C tablets* would be efficacious in the treatment and prevention of gingivitis, dental caries, pyorrhea, gum infections, anorexia, anemia, undernutrition, and infections; that it would be efficacious to combat common colds; and that it would be efficacious to counteract body poisons and nutritional oral and tooth deficiencies.

DISPOSITION: June 29, 1950. Pleas of nolo contendere having been entered, the court imposed a fine of \$1,000, plus costs, against the defendants jointly.

3195. Misbranding of Vita-Pep tablets. U. S. v. 41 Boxes * * *. (F. D. C. No. 29341. Sample No. 72745-K.)

LIBEL FILED: May 26, 1950, Southern District of Ohio.

ALLEGED SHIPMENT: On or about December 16, 1949, from Baltimore, Md.

PRODUCT: *Vita-Pep tablets*. 41 boxes, each containing 50 tablets, at Columbus, Ohio, in possession of the May Drug Co., together with a placard relating to the product headed "Restore Youth and Vitality."

RESULTS OF INVESTIGATION: The May Drug Co. received the product in bottles of 5,000 tablets each, but none of the tablets remained on hand in the original containers, all having been repackaged into boxes labeled as described below. Also in possession of the consignee at its store was a placard displayed in the window, together with dummy boxes used in packaging the tablets. The placard read, in part: "Restore Youth and Vitality."

Analyses showed that the article contained alkaloids of nux vomica in very small amounts, together with zinc phosphide and unidentified organic matter.

LABEL, IN PART: (Boxes) "Vita-Pep Tablets For Better Health Life Begins At Forty Vita-Pep is the perfect tonic for persons approaching middle age. Restores energy and will help you to enjoy life. Distributed by May Laboratories Columbus, Ohio."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the label of the article and on the accompanying placard were false and misleading.

The statements represented and suggested that the article would restore youth and vitality, correct loss of appetite, nervousness, and weak glands, and improve health; that it was a perfect tonic for persons approaching middle age; and that it would restore energy and help one to enjoy life. The article was not capable of fulfilling the promises of benefit stated and implied.

Further misbranding, Section 502 (e) (2), the label of the article failed to bear the name of each active ingredient since its label failed to bear the name of any active ingredient.

The article was misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: June 23, 1950. Default decree of destruction.

3196. Misbranding of homeopathic mineral tablets. U. S. v. 33 Boxes, etc. (F. D. C. No. 29068. Sample Nos. 70071-K to 70082-K, incl.)

LABEL FILED: April 26, 1950, Western District of Oklahoma.

ALLEGED SHIPMENT: On or about March 21, 1950, by Luyties Pharmacal Co., from St. Louis, Mo.

PRODUCT: 33 boxes of *calcareae fluor.* (calcium flouride) tablets, 15 boxes of *calcareae phos.* (calcium phosphate) tablets, 24 boxes of *calcareae sulph.* (calcium sulfate) tablets, 31 boxes of *ferrum phos.* (iron phosphate) tablets, 35 boxes of *kali mur.* (potassium chloride) tablets, 33 boxes of *kali phos.* (potassium phosphate) tablets, 12 boxes of *kali sulph.* (potassium sulfate) tablets, 18 boxes of *magnesiae phos.* (magnesium phosphate) tablets, 47 boxes of *natrum mur.* (sodium chloride) tablets, 22 boxes of *natrum phos.* (sodium phosphate) tablets, 11 boxes of *natrum sulph.* (sodium sulfate) tablets, and 36 boxes of *silicea* (silicic acid) tablets, and 274, more or less, books entitled "Universal Mineral Food Co. Text Book," at Oklahoma City, Okla.

RESULTS OF INVESTIGATION: Investigation disclosed that these drugs had been shipped in bulk from the Luyties Pharmacal Co. and were repackaged by the consignee in retail boxes which had been supplied to the consignee by the Luyties Pharmacal Co. The books in possession of the consignee consisted of 138 pages and had been prepared by the consignee, the Universal Mineral Food Co., Inc., from copy prepared by an officer of that corporation.

Analyses indicated that the tablets possessed the compositions stated upon their respective labels.

LABEL, IN PART: (Box) "Tablets * * * Containing Homeopathic Calcarea Fluor. 6x (Calcium Fluoride) [or "Calcarea Phos. 3x (Calcium Phosphate)," "Calcarea Sulph. 3x (Calcium Sulphate)," "Ferrum Phos. 3x (Iron Phosphate)," "Kali Mur. 3x (Potassium Chloride)," "Kali Phos. 3x (Potassium Phosphate)," "Kali Sulph. 3x (Potassium Sulphate)," "Magnesia Phos. 3x (Magnesium Phosphate)," "Natrum Mur. 6x (Sodium Chloride-Salt)," "Natrum Phos. 3x (Sodium Phosphate)," "Natrum Sulph. 3x (Sodium Sulphate)," and "Silicea 6x (Silicic Acid)"]]"

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the box labels of the articles and in the accompanying book were false and misleading since the articles were not adequate and effective treatments for the conditions represented and suggested by such statements. The statements represented and suggested that the tablets were adequate and effective treatments for the following conditions: (*calcareae fluor.*) varicose veins, itching or bleeding hemorrhoids, asthma, appendicitis, constipation, curvature of the

spine, enlarged heart, valvular heart leakage, floating kidney, female troubles, fallen uterus, piles, tumors, enlarged tonsils, and swollen glands; (calcareo phos.) anemia, delayed dentition, diarrhea, backache, bladder stones, curvature of the spine, abscess or tuberculosis of the bone, Bright's disease, chronic diseases, colic, constipation, tuberculosis, diabetes, dropsy, gallstones, menstrual disorders, rickets, and cancer; (calcareo sulph.) skin eruptions, catarrh, cough, ulceration of the teeth, bleeding gums, sick stomach, all ulcerations, chronic inflammation, chronic hip joint disease, bone ulcers, tuberculosis of the bone, and smallpox; (ferrum phos.) fever, colds, nosebleed, cough, inflammation, soreness, hemorrhage, pneumonia, diphtheria, tuberculosis, blood poison, every disease in the acute form where a raging high fever becomes the crisis, felon, cancer, abscess, rheumatism, smallpox, and nephritis; (kali mur.) catarrh, coughs, indigestion, diarrhea, mumps, scarlet fever, measles, chicken pox, diphtheria, croup, membranous croup, pneumonia, syphilis, gonorrhea, bubo, chancre, cancer, and smallpox; (kali phos.) nervousness, restlessness, sleeplessness, discharges from any organ of the body, cholera, locomotor ataxia, muscular weakness, bloody dysentery, itching piles, mental derangements, foul discharges from ears, loss of sight from diphtheria, brain fever, palpitation of the heart, paralysis, infantile paralysis, smallpox, alcoholism, and rickets; (kali sulph.) catarrh, coughing spells and oppressed breathing, hard, hoarse, or croupy cough, eczema, asthma, bronchitis, cancer, consumption, measles, scarlet fever, typhoid, pneumonia, smallpox, and nephritis; (magnesia phos.) neuralgic pains and headaches, bloat, colic, cramps, acute cough, enuresis, convulsions, stammering, stuttering, spasms, fits, epilepsy, lockjaw, St. Vitus' dance, palsey, and nephritis; (natrum mur.) colds, throat and bronchial irritations, hay fever, dropsy, dysentery, sunstrokes, diabetes, cancer, chronic skin diseases, ringworm, and shingles; (natrum phos.) diarrhea, sour vomiting, muscular pains, diabetes, erysipelas, female trouble, scrofula, eczema, worms, and pyorrhea; (natrum sulph.) bilious headaches, colds, colic, chills, diarrhea, disordered stomach, coated tongue, vomiting of bile, yellowish skin, dizziness, flu, la grippe, diabetes, liver trouble, gall bladder and pancreatic disturbances, painter's colic, jaundice, malaria, yellow fever, erysipelas, and ringworm; and (silicea) boils, ulcerations, ailments attended with pus formation, chronic catarrh, all deep-seated pus in the blood, chronic skin diseases, gouty, rheumatic troubles, falling hair, heavy headache, leprosy, sty on the eyelid, felons, measles, smallpox, and rickets.

The articles were misbranded when introduced into, while in, and while held for sale after shipment in, interstate commerce.

DISPOSITION: May 31, 1950. The Universal Mineral Food Co., Inc., claimant, having admitted the allegations of the libel, judgment of condemnation was entered and the court ordered that the products be released under bond for relabeling, under the supervision of the Federal Security Agency.

3197. Misbranding of Facial and Body Genie device. U. S. v. 1 Device, etc. (F. D. C. No. 27851. Sample No. 1870-K.)

LIBEL FILED: On or about September 30, 1949, Southern District of Florida.

ALLEGED SHIPMENT: On or about May 10, 1949, by Harvey, Inc., from Macon, Ga.

PRODUCTS: 1 *Facial and Body Genie device* at Coral Gables, Fla., together with an accompanying booklet, a white leaflet, and a yellow leaflet, all entitled "Facial and Body Genie."

The device was an electrical apparatus utilizing 110-volt, 60-cycle alternating current, supplied from an ordinary wall socket. It operated as a pulsed electronic oscillator, and was equipped with attachments for applying the output to various parts of the skin of a patient. Controls on the front panel of the device provided a means for controlling the pulse rate and voltage output. The physiological effect of the device when used as directed was a pulsed electrical stimulation of various parts of the human body.

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements and designs in the accompanying booklet and leaflets were false and misleading since the device was not effective for the purposes stated and implied. The statements and designs represented and suggested that the device would be efficacious for facial rejuvenation and for removing wrinkles; that involuntary muscles around the eyes and mouth could be exercised perfectly by use of the device; that the device was primarily useful in helping the muscles of the face, bust, and stomach which have become small and flabby; that it would firm and tighten the stomach and bust muscles and strengthen the foot and leg muscles; that it was the key to youthful contour; that it would soften the wrinkles that years and worry add; and that it would give the natural elasticity of youth to hold sagging cheeks, drooping mouth lines, and chins more firmly in place.

DISPOSITION: A motion to dismiss the libel was filed on behalf of Harvey, Inc., on the grounds that the libel was insufficient to state a cause of action; that the material contained in the booklet and leaflets was not attached to or made a part of the device; and that the libel failed to show in what respects the statements in such booklet and leaflets were false and misleading.

On December 2, 1949, a hearing was held on the motion to dismiss, at the conclusion of which the court entered an order denying the motion. An answer was thereupon filed on behalf of Harvey, Inc., denying that the device was misbranded. Thereafter, Harvey, Inc., consented to the entry of a decree; and, accordingly, on August 24, 1950, judgment of condemnation was entered and the court ordered that the device be delivered to the Food and Drug Administration.

DRUGS FOR VETERINARY USE

3198. Misbranding of Super Culture all purpose feed and Special dairy feed.

U. S. v. William Hite (Super Culture Sales Co.); (2 informations).

Plea of guilty. Imposition of sentence suspended and defendant placed on probation for 2 years. (F. D. C. Nos. 25567, 25575. Sample Nos. 24397-K to 24399-K, incl.)

INFORMATIONS FILED: November 24, 1948, and March 14, 1949, District of Minnesota, against William Hite of Mankato, Minn., trading as the Super Culture Sales Co. at Sioux City, Iowa.

INTERSTATE SHIPMENT: On or about December 9, 1946, and July 2 and September 22, 1947, from the State of Iowa into the State of Minnesota.

ALLEGED VIOLATION: (First information). Between the approximate dates of December 15, 1946, and December 12, 1947, while the *Super Culture all purpose feed* was being held for sale after shipment in interstate commerce, the defendant, at Lake Crystal, Minn., caused certain circulars entitled "Super Culture Feed" and "Guarantee And Refund Contract" to accompany the article, which act resulted in the article being misbranded.

(Second information). On or about September 23, 1947, the defendant received a quantity of *Special dairy feed* in interstate commerce at Mankato, Minn., from Sioux City, Iowa, and proffered and delivered such article for pay or otherwise.

PRODUCT: Analyses disclosed that the *Super Culture all purpose feed* consisted of a reddish-colored mixture containing protein (14.90% and 16.51%, respectively, in 2 samples), crude fiber and crude fat, together with salt, soda, iron oxide, and cereal bran; and that the *Special dairy feed* consisted essentially of a reddish-colored mixture containing 18.60% sulfanilamide and 10.00% protein, and crude fiber and crude fat, together with salt, soda, iron oxide, cereal bran, and anise.

NATURE OF CHARGE: *Super Culture all purpose feed.* Misbranding, Section 502 (a), certain statements in the circulars accompanying the article were false and misleading. The statements represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of flu, spleen trouble, rickets, abortion, jaundice, worms, and necro in hogs; that the article would get hogs in a healthy condition; that it would prevent bowel trouble in chicks and increase the egg production of hens; that the article when used in conjunction with a product known as "Special Dairy Culture" or "Special Dairy Feed" would be efficacious in the cure, mitigation, treatment, and prevention of mastitis; that the article would eliminate and correct 80 percent of the dietary troubles and diseases which produce unthriftiness in hogs; and that it would be efficacious in the prevention of white diarrhea, necro, enlargement of the spleen, flu, and worms in brood sows, pigs, and shoats. The article would not be efficacious for the purposes so represented and suggested.

Special dairy feed. Misbranding, Section 502 (a), certain statements on bags containing the article and upon tags attached to such bags were false and misleading. The statements represented and suggested that the article would be efficacious in the treatment of mastitis, whereas the article would not be efficacious for that purpose.

The articles were alleged to be misbranded also under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: On June 7, 1950. A plea of guilty having been entered, the court suspended the imposition of sentence on each information and placed the defendant on probation for 2 years.

3199. Misbranding of Breed. U. S. v. 24 Pails * * *. (F. D. C. No. 29313. Sample No. 77226-K.)

LABEL FILED: May 15, 1950, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about March 31, 1950, by Breed, Inc., from Galesburg, Ill.

PRODUCT: 24 25-pound pails of Breed at St. Louis, Mo.

LABEL, IN PART: (Tag) "Breed for Calves - Hogs - Poultry - Dairy Cows - Feeder Cattle * * * Ingredients Dried Whole Milk, Wheat Germ Oil, Riboflavin, Dried Buttermilk, Dried Whey, Starch, Choline Chloride, Thiamin, Niacin, Pantothenic Acid, Salt, Yeast, Iron Oxide, Anise, Iron Sulphate, Blood Flour, St. Johns bread, Ginger, Powdered (Vit. A), (D₂), Activated Animal Sterol, Red Dog, Cobalt, Calcium Carbonate, Iodide, Boron, Spent Bone Black, Manganese Sulphite, Copper Sulphate, Dried Fish Soluble."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements in the labeling of the articles were false and misleading since the article was not capable of accomplishing the results stated and implied by such statements. The statements represented and suggested that calves would seldom scour when the article was fed to them; that the article would insure healthy litters from sows; that it would help reduce baby chick fatalities; that by adding the article to the dairy ration, dairy cows would have a higher disease resistance and would be in better condition to assimilate their feed and turn it into butterfat and milk production; and that the article would tend to keep sows healthy and insure a good flow of milk when they farrow.

DISPOSITION: June 15, 1950. Default decree of condemnation and destruction.

3200. Adulteration and misbranding of Spear egg mash. U. S. v. 15 Bags, etc.
(F. D. C. No. 29095. Sample Nos. 70959-K, 70960-K.)

LABEL FILED: May 5, 1950, District of Kansas.

ALLEGED SHIPMENT: On or about March 16, 1950, by Spear Mills, Inc., from Kansas City, Mo.

PRODUCT: 32 bags of *Spear egg mash* at Kansas City, Kans. Examination showed that the product contained not more than 127 grains of nicotine and not more than 563 grains of phenothiazine per 100 pounds.

LABEL, IN PART: "Spear Egg Mash [or "Spear 'All Mash' Egg Mash"] with Worm Control for Large Round Worms and Cecal Worms Active Ingredients: Nicotine as Alkaloid 175 grains and Phenothiazine 600 grains per 100 lbs."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess, namely, "Nicotine as Alkaloid 175 grains and Phenothiazine 600 grains per 100 lbs."

Misbranding, Section 502 (a), the statements "Egg Mash with Worm Control for Large Round Worms and Cecal Worms * * * it has the Spear Worm Control Formula built-in the feed as an effective treatment against large round worms and cecal worms," appearing on the tag attached to the bags, were false and misleading since the article when used as directed, namely, "It is to be fed 5 consecutive days each month in place of regular Spear * * * Feeds. It is not necessary to feed this special feed more than 5 days each month," would not constitute an effective control or treatment of large round worm and cecal worm infestation of poultry.

DISPOSITION: June 24, 1950. Default decree of condemnation and destruction.

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PRODUCTS

	N. J. No.		N. J. No.
Acidofilac -----	¹ 3190	Celery Fruit (celery seed), Fluid	
Amberin -----	² 3193	Extract No. 118; and Celery	
Antihistamine tablets -----	3183	Compound, Green's -----	3188
Arthritis, remedies for -----	3187, 3188	Crema-A-Tone -----	3191
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Calcium fluoride tablets, calcium		Egg mash, Spear -----	3200
phosphate tablets, and cal-		Elgyn capsules -----	3191
cium sulfate tablets -----	3196		

¹ (3190) Permanent injunction issued.

² (3193) Prosecution contested.

	N. J. No.		N. J. No.
Estra-Beta capsules-----	3191	Seconal Sodium capsules-----	3185
Facial and Body Genie device---	3197	Silicic acid tablets-----	3196
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Folitrin tabsules-----	3191	phosphate tablets, and so-	
Gattis worm oil-----	3182	dium sulfate tablets-----	3196
Genie, Facial and Body (device)-	3197	Spear egg mash-----	3200
Green Dragon liniment-----	3189	Special dairy feed-----	3198
Green's Celery Compound-----	3188	Stops (antihistamine tablets)---	3183
Hemorrhoids, remedy for----- ²	3193	Sulfadiazine tablets-----	3185
Homeopathic mineral tablets---	3196	Sulfathiazole tablets-----	3186
Iron phosphate tablets-----	3196	Super Culture all purpose feed--	3198
Liniment, Green Dragon-----	3189	Testosterone, methyl, tablets---	3181
Magnesium phosphate tablets---	3196	Thyroid tablets-----	3185
Methyl testosterone tablets---	3181	Trestilon tablets-----	3191
Pentobarbital sodium capsules--	3184	Veterinary preparations-----	3198-3200
Potassium chloride tablets, potas-		Vextrin capsules-----	3191
sium phosphate tablets, and		Vitamin preparations-----	3194
potassium sulfate tablets----	3196	Vita-Pep tablets-----	3195
Private Formula tablets-----	3187	ViViBx tablets and ViViBx cap-	
Prophylactics-----	3192	sules-----	3194
Pruvo tablets-----	3187	Worms, remedies for-----	3182
Rheumatism, remedies for--	3187, 3188	(veterinary use)-----	3200

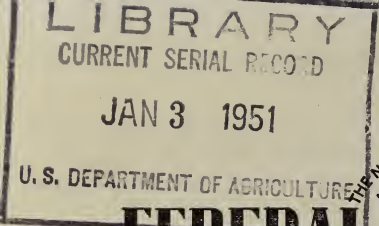
SHIPPERS, MANUFACTURERS, AND DISTRIBUTORS

	N. J. No.		N. J. No.
Albright, Frank:		Green Drug Co. <i>See</i> Green Lab-	
sulfadiazine tablets, Seconal		oratories.	
Sodium capsules, and thyroid		Green Laboratories:	
tablets-----	3185	Fluid Extract No. 118 Celery	
Albright Drug Store. <i>See</i> Al-		Fruit (celery seed) and	
bright, Frank.		Green's Celery Compound---	3188
Amberin Co. <i>See</i> Brownlow,		Harvey, Inc.:	
B. A.		Facial and Body Genie device--	3197
Bowers, C. A.:		Herrschnor, Frederick:	
sulfathiazole tablets-----	3186	ViViBx tablets and ViViBx	
Bowers' Pharmacy:		capsules-----	3194
sulfathiazole tablets-----	3186	Hite, William:	
Breed, Inc.:		Super Culture all purpose feed	
Breed-----	3199	and Special dairy feed----	3198
Brownlow, B. A.:		International Pharmaceutical	
Amberin----- ²	3193	Co.:	
Dean Rubber Mfg. Co.:		ViViBx tablets and ViViBx	
prophylactics-----	3192	capsules-----	3194
Gattis Chemical Co.:		Lilly, Eli, & Co.:	
Gattis worm oil-----	3182	Fluid Extract No. 118 Celery	
Green Dragon Medicine Co.:		Fruit (celery seed) and	
Green Dragon liniment-----	3189	Green's Celery Compound---	3188

² (3193) Prosecution contested.

	N. J. No.		N. J. No
Luyties Pharmacal Co.:		Research Associates:	
homeopathic mineral tablets--	3196	Stops (antihistamine tablets)-	3183
May Drug Co.:		SLK, Wm., Laboratories:	
Vita-Pep tablets-----	3195	Private Formula tablets-----	3187
May Laboratories:		Spear Mills, Inc.:	
Vita-Pep tablets-----	3195	Spear egg mash-----	3200
Needman, Louis:		Standard Pharmacal Co.:	
methyl testosterone tablets---	3181	Private Formula tablets and	
Newell, C. T.:		Pruvo tablets-----	3187
pentobarbital sodium capsules-	3184	Stofel, Al:	
Oxford Products, Inc.:		Green Dragon liniment-----	3189
Crema-A-Tone, Vextrin cap-		Super Culture Sales Co. <i>See</i>	
sules, Trestilon tablets, El-		Hite, William.	
gyn capsules, Folitrin tab-		Universal Mineral Food Co., Inc.:	
sules, Slix tablets, and Estra-		homeopathic mineral tablets--	3196
Beta capsules-----	3191	Walters, H. A.:	
Pruvo Pharmacal Co.:		Acidofilac -----	¹ 3190
Private Formula tablets and		West Coast Prescription Phar-	
Pruvo tablets-----	3187	macy. <i>See</i> Needman, Louis.	
Radiance Products Co. <i>See</i> Wal-			
ters, H. A.			

¹ (3190) Permanent injunction issued.



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